JEFFREY B. COOPERSMITH (SBN 252819)
AMY WALSH (Admitted Pro Hac Vice)
STEPHEN A. CAZARES (SBN 201864)
ORRICK, HERRINGTON & SUTCLIFFE LLP
The Orrick Building
405 Howard Street
San Francisco, CA 94105-2669
Telephone: (415) 773-5700
Facsimile: (415) 773-5759

Email: jcoopersmith@orrick.com; awalsh@orrick.com; scazares@orrick.com

Attorneys for Defendant
RAMESH "SUNNY" BALWANI

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. RAMESH "SUNNY" BALWANI, Defendant.	Case No. CR-18-00258-EJD **DEFENDANT RAMESH "SUNNY" BALWANI'S OMNIBUS MOTIONS IN LIMINE** **Date: December 16, 2021** **Time: 9:00 a.m.** **CTRM.: 4, 5th Floor** **Hon. Edward J. Davila**

NOTICE OF MOTIONS AND MOTIONS

PLEASE TAKE NOTICE that on December 16, 2021, at 9:00 a.m., or at such later date and time as the Court may order, in Courtroom 4 of the above-captioned Court, 280 South 1st Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Ramesh "Sunny" Balwani will and hereby does move this Court for the following evidentiary orders:

1. Excluding evidence relating to the accuracy and reliability of blood tests offered by Theranos that were run on unmodified commercial devices pursuant to Federal Rules of Evidence 104 and 401–403;
2. Excluding any testimony of Dr. Kingshuk Das concerning his views on the accuracy and reliability of tests conducted at Theranos, including but not limited to the voiding of tests or Dr. Das' views on reasons for voiding tests;
3. Excluding evidence of Theranos' voiding of test results pursuant to Federal Rule of Evidence 407;
4. Excluding certain alleged coconspirator statements that are outside the timeframes of the charged conspiracies and therefore inadmissible under Federal Rule of Evidence 801(d)(2)(E);
5. Excluding any expert testimony offered by lay witnesses, including but not limited to any such testimony from witness Erika Cheung;
6. Excluding certain text messages under Federal Rules of Evidence 401–403;
7. Excluding evidence of Mr. Balwani's license plate or car under Federal Rules of Evidence 401–403;
8. Granting all other relief as requested in Mr. Balwani's motion in limine adopting in full certain motions previously filed by Defendant Elizabeth Holmes.

These motions are based on this notice, the accompanying memorandum of points and authorities, the declaration of Jeffrey B. Coopersmith, the files and records in this matter, and on such further argument and evidence as may be presented before and during the hearing.

Dated: November 19, 2021

Respectfully submitted,

ORRICK HERRINGTON & SUTCLIFFE LLP

By: */s/ Jeffrey B. Coopersmith*
Jeffrey B. Coopersmith

Attorney for Defendant
RAMESH "SUNNY" BALWANI

TABLE OF CONTENTS

TABLE OF CONTENTS
(CONTINUED)

Page

TABLE OF CONTENTS
(CONTINUED)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Court Rules

Regulations

Other Authorities

MEMORANDUM OF POINTS AND AUTHORITIES

MOTION IN LIMINE NO. 1 TO EXCLUDE EVIDENCE OF ACCURACY AND RELIABILITY OF TESTS RUN ON UNMODIFIED COMMERCIAL DEVICES

The government's conspiracy and wire-fraud case against Defendant Ramesh "Sunny" Balwani centers on the allegation that Mr. Balwani represented to patients and investors that Theranos' blood tests were accurate and reliable when "Theranos's technology was, in fact, not capable of consistently producing accurate and reliable results." Third Superseding Indictment ("Indictment" or "TSI") ¶¶ 12(A), 12(C), 12(F), 12(H), 15, 16, 17(C). Mr. Balwani expects the government will attempt to prove that allegation through the testimony of Theranos patients, former Theranos employees, and regulators, as well as through exhibits, including the January 25, 2016 Centers for Medicare & Medicaid Services ("CMS") Form 2567 and cover letter.

The Indictment's allegations about accuracy and reliability relate solely to "Theranos's technology." The Indictment does not allege anything about the accuracy and reliability of non-Theranos technology, i.e., commercially available blood analyzers used by Theranos in its clinical laboratories that Theranos did not modify. Nor does the Indictment allege anything about the general practices of the Theranos clinical labs. Because the government's allegations are limited to the accuracy and reliability of Theranos' technology, any evidence the government offers related to accuracy or reliability must be tied to that technology, and the government must be able to lay the requisite foundation to establish that fact. Conversely, evidence regarding accuracy or reliability that relates to non-Theranos technology is not relevant and should not be admitted into evidence.

Accordingly, Mr. Balwani moves under Federal Rules of Evidence 104, 401, 402, and 403 to exclude evidence relating to the accuracy and reliability of blood tests offered by Theranos that were not run on "Theranos's technology," or for which the government cannot lay the requisite foundation establishing that the tests were run on "Theranos's technology." This evidence includes testimony from Patients E.T. and B.B., as well as portions of the CMS Form 2567 and

cover letter.[1] Unless and until the government can establish that a given piece of evidence is related to the accuracy and reliability of "Theranos's technology," that evidence is not relevant to the allegations in the Indictment, and therefore is inadmissible.

I. FACTUAL BACKGROUND

As the Court is aware, the Indictment charges two fraudulent schemes—a scheme to defraud investors and a scheme to defraud patients. Based on the language in the Indictment, both alleged schemes to defraud turn on the allegation that Theranos' proprietary tests were not capable of producing accurate and reliable results. As to the alleged scheme to defraud patients, the Indictment alleges that Mr. Balwani made representations about the capability of Theranos' technology that were false:

> "BALWANI knew . . . that *Theranos's technology* was, in fact, not capable of consistently producing accurate and reliable results."

TSI ¶ 16 (emphasis added); *see also* TSI ¶ 15 (alleging misrepresentations and omissions about "Theranos's technologies"); ¶ 17(C) (alleging transmission to patients of inaccurate and unreliable tests results performed on "Theranos technology"). For the alleged scheme to defraud investors, the Indictment similarly describes as false Mr. Balwani's representations about "the TSPU, Edison, or Minilab," as well as Mr. Balwani's representations about "Theranos's proprietary analyzer." *Id.* ¶¶ 12(A), 12(C), 12(F), and 12(H).

As the Court heard during Ms. Holmes' trial, Theranos began offering patient testing in Walgreens pharmacies in the fall of 2013. Ex. 1 (9/24/21 Trial Tr. 1711:7–12). Once patient testing began, Theranos ran the patient blood samples on three types of analyzers: (1) the Theranos Sample Processing Unit ("TSPU"); (2) commercial analyzers that were modified by Theranos to be able to analyze small quantities of blood ("modified commercial devices"); and

[1] This motion focuses on the evidence from Patients E.T., B.B., and the CMS Form 2567. The defense does not know yet what other evidence unrelated to the accuracy and reliability of "Theranos's technology" the government will offer at trial. If the government offers other inadmissible evidence, and the government cannot lay sufficient foundation to link it to the accuracy and reliability of "Theranos's technology," Mr. Balwani intends to object to its admission at trial.

(3) commercial FDA-cleared or approved analyzers that were not modified ("unmodified commercial devices"). *Id.* (1712:5–1715:14; 1719:10–23). Theranos also sent samples to third-party reference laboratories when it could not perform the test itself. *Id.* (9/14/21 Trial Tr. 813:19–23). The TSPU and the modified commercial devices were Theranos's proprietary technology that the company developed and for which it held patents. Ex. 2 (DX 07709). The unmodified commercial devices (and third party send-outs) were not "Theranos's technology," as the government itself has emphasized throughout Ms. Holmes' trial. *See, e.g.*, Ex. 1 (9/14/21 Trial Tr. 800:6–10, 806:23–807:3, 813:11–814:4) (government asking Erika Cheung about "the devices that Theranos manufactured, [namely] the Edison" and "devices that were not invented or manufactured by Theranos").

II. ARGUMENT

Evidence is relevant only if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. If evidence does not pass this standard, it is inadmissible. Fed. R. Evid. 402. Moreover, even if evidence meets the threshold relevance requirement, the Court may exclude the evidence if its probative value is substantially outweighed by a danger of unfair prejudice, confusing the issues, or misleading the jury. Fed. R. Evid. 403. Evidence is unfairly prejudicial when it has "an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." *United States v. Pac. Gas & Elec. Co.*, 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016) (quoting *Old Chief v. United States*, 519 U.S. 172, 180 (1997)).

On the question of accuracy and reliability, the Rule 401 "fact" that is of consequence is whether Theranos' technology was capable of producing accurate and reliable test results. The TSI only takes issue with Theranos' allegedly false representations regarding the accuracy, reliability, speed, and cost of blood tests conducted on Theranos technology. TSI ¶¶ 12(A), 12(C), 12(F), 12(H), 15, 16, 17(C). The TSI does not allege that Mr. Balwani committed any crime regarding the accuracy and reliability of non-Theranos technology, nor does the TSI comment on the general practices of the Theranos lab. Accordingly, the only evidence that is relevant to the alleged misrepresentations is evidence about the accuracy and reliability of tests that the

government can prove actually were run on "Theranos's technology."

What this means in concrete terms is that for every piece of evidence offered against Mr. Balwani regarding the accuracy and reliability of Theranos' blood tests, Federal Rules of Evidence 104 and 401 require the government to lay sufficient foundation linking that evidence to the allegations in the Indictment—i.e., the accuracy and reliability of "Theranos's technology." If the government cannot lay that foundation, the evidence must be excluded under Rules 104, 401, 402 and 403. If a given test offered by Theranos was run on an unmodified commercial device, or if the government cannot establish that the test was run on Theranos technology, any evidence about that test should be excluded as irrelevant and unfairly prejudicial because it does not constitute evidence of the inaccuracy of Theranos' technology.

Accordingly, Mr. Balwani moves this Court to exclude evidence relating to the accuracy and reliability of blood tests not run on "Theranos's technology." This includes the evidence discussed below on Patients E.T. and B.B., and portions of the January 25, 2016 CMS Form 2567 and cover letter. Mr. Balwani reserves his right to move to exclude any other evidence offered by the government related to the allegation of inaccuracy and unreliability where the government cannot connect that evidence to a test run on a Theranos proprietary device.

A. Patient E.T. Must Be Excluded

Patient E.T. received a blood test offered by Theranos during her annual physical with her primary care physician. Ex. 3 (US-REPORTS-0015081 at 2–3). Patient E.T.'s blood test included a screening for HIV. *Id.* Patient E.T. is the patient alleged in Count 10 of the Indictment and the defense expects the government to call Patient E.T. to establish that Patient E.T.'s test results were inaccurate. TSI ¶ 26.

Despite the implication in the Indictment that HIV tests were run on Theranos technology, that is not the case. The HIV testing offered by Theranos was never run on Theranos technology. Throughout the period of Theranos' patient testing, HIV tests offered by Theranos were run only on unmodified commercial devices. *See* Ex. 5 (US-FDA-0015698). These non-Theranos devices included the OraSure OraQuick Advance Rapid HIV 1/2 AB Test Kit, Bio-Rad Multispot HIV 1/HIV 2 Rapid Test, BioRad Evolis, Siemens Centaur XP, and Abbott M2000 Real Time PCR.

Exs. 6–10 (Government trial exhibits 0428, 0808, 1862, 1927, 5062). The government is aware of this fact as its own proposed exhibit list for Mr. Balwani's trial reflects SOPs and package inserts about these unmodified commercial devices used for HIV testing. *Id.*

As a result, Patient E.T.'s testimony does not relate to the accuracy and reliability of "Theranos's technology" and is therefore inadmissible, as is any other evidence relating to HIV testing offered by Theranos. The government cannot lay a foundation linking Patient E.T.'s testimony about her HIV test result to "Theranos's technology." Fed. R. Evid. 104(b); *see also Huddleston v. United States*, 485 U.S. 681, 690 (1988) ("In determining whether the Government has introduced sufficient evidence to meet Rule 104(b), the trial court . . . examines all the evidence in the case and decides whether the jury could reasonably find the conditional fact . . . by a preponderance of the evidence."). The relevance of Patient E.T.'s testimony on the accuracy and reliability of her HIV test "depends on whether a fact exists," namely that the tests were run using "Theranos's technology." *See* Fed. R. Evid. 104(b). Since the government cannot lay that required foundation, evidence regarding the accuracy and reliability of Patient E.T.'s HIV test results from an unmodified commercial device makes no fact related to Mr. Balwani's guilt or innocence more or less likely. *See* Fed. R. Evid. 401, 402.

Moreover, Patient E.T.'s testimony that she received an allegedly erroneous Theranos test indicating that she was HIV-positive is highly prejudicial. Indeed, during the Holmes trial, the government asked Patient E.T. whether she was had ever been diagnosed with "HIV or AIDS," whether she had experienced symptoms of "HIV or AIDS," and whether she had ever received treatment for "HIV or AIDS." Ex. 1 (11/17/21 Trial Tr. 6756:19–6757:4). Her testimony should be excluded because Patient E.T.'s testimony has no probative value whatsoever. Her test was a non-Theranos test. It has nothing to do with the Indictment's allegations on the accuracy and reliability of "Theranos's technology." Fed. R. Evid. 403; *United States v. McFayden-Snider*, 552 F.2d 1178, 1184 (6th Cir. 1977) (where "proffered evidence concerns misconduct other than that charged in the indictment, it is inadmissible when the resulting prejudice would be too great").

There is no cross examination of this witness that could cure the unfair prejudice cemented during the government's direct examination. Once the jury hears that this patient

received an allegedly inaccurate test from Theranos indicating that she might be positive for HIV—even if the test was not run on Theranos technology—the irreversible damage is done.

In addition, testimony from a patient regarding the accuracy and reliability of non-Theranos tests will be highly misleading and confusing. *See United States v. Robertson*, 875 F.3d 1281, 1296 (9th Cir. 2017) (affirming the district court's decision to exclude evidence that confused the jury), *vacated on other grounds*, 139 S. Ct. 1543 (2019). The jury will likely assume that since Patient E.T. was allowed to testify, Patient E.T.'s test must have been performed on Theranos technology, when in fact that is not true. If Patient E.T.'s testimony comes in, the jury will need to parse through the evidence to determine which evidence relates to the accuracy and reliability of "Theranos's technology" (which is relevant to the allegations) and which evidence relates to the accuracy and reliability of non-Theranos technology (which is not relevant to the allegations). For these reasons, Patient E.T.'s testimony about her HIV test run on an unmodified commercial device is inadmissible and must be excluded.

B. Patient B.B. Must Be Excluded

1. Patient B.B. Must be Excluded Because His Test Was Not Run on Theranos Technology

Patient B.B. was a patient who had been diagnosed with essential thrombocythemia, which required him to regularly monitor his blood platelet count. Patient B.B. received four complete blood count ("CBC") tests, which included platelet counts, from Theranos on August 11, August 21, August 27, and December 11, 2015. Ex. 4 (US-REPORTS-0015058). The defense expects Patient B.B. to testify that his first test was run using a fingerstick draw and the platelet count result within the CBC test was suspiciously high. His other three CBC tests were run with venous draw. *Id.* The only test report the defense knows of for Patient B.B. is a test report for his August 27, 2015 visit, which suggests that this test was processed in Theranos' Arizona laboratory—a lab that used only unmodified commercial devices. "Theranos's technology" was not used in the Arizona lab. The defense knows of no test report or other document for Patient B.B. that establishes that the test that he is expected to testify about as inaccurate was run on a Theranos analyzer.

Theranos' CBC panel was run using three devices—only one of which was "Theranos's technology." Specifically, the lab processed traditional venous samples on an unmodified Siemens Advia 2120—not Theranos technology. Ex. 11 (THPFM0003814256). The lab also used two analyzers for processing fingerstick samples—the Drew3 and the BD Fortessa. The Drew3 was an unmodified commercially available hematology platform capable of processing fingerstick samples. Ex. 12 (THPFM0005699178). The Drew3 also was not Theranos technology. *Id.* The BD Fortessa was a commercial device running Theranos developed assays, and thus was Theranos technology. Exs. 13–15 (Government trial exhibits 1111, 2685, and THPFM0002267542).

Due in part to the loss of laboratory data in the Laboratory Information System ("LIS"), which included identification of the analyzer and blood collection device used for any test, the defense is unaware of evidence that would identify which device was used for Patient B.B.'s first test that he claims was processed from a fingerstick sample. As a result, Patient B.B.'s first test may have been run on the unmodified Drew3 or the modified Fortessa. In fact, the CMS survey report that has been the subject of much litigation in this case reflects that Theranos was using two Drew3 devices to process fingerstick samples for CBC testing in the July to September 2015 time frame. Ex. 20 (Holmes Tr. Ex. 4621B) (*see* tags D5437, D5469, D5779, D6178). Thus, the government well knows that Theranos was using the unmodified Drew3 analyzer to process fingerstick samples for CBC when Patient B.B. obtained his first fingerstick test in August 2015. Moreover, the fact that Patient B.B.'s three other CBC tests were venous draws clearly indicates that they were not run on Theranos technology.

For the same reasons articulated above for patient E.T., unless the government can lay a proper foundation linking evidence regarding the accuracy and reliability of patient B.B.'s test results to the accuracy and reliability of "Theranos's technology," it is inadmissible under Rules 104(b), 401, 402, and 403.

2. The Government's Amended Bill of Particulars Is No Cure

On May 22, 2021, this Court granted Ms. Holmes' motion in limine to exclude accuracy and reliability evidence for any assays not reflected in the government's March 23, 2020 Bill of Particulars ("BoP") and the Indictment.[2] Dkts. 568, 798. On November 3, 2021, the Court also granted Ms. Holmes' motion to exclude testimony by Patient B.B. because the assay at issue for this patient, the platelet component of a CBC test, was not included in the BoP or Indictment and was thus already excluded by the Court when it granted the motion in limine. Dkt. 1126; Ex. 1 (11/3/21 Trial Tr. 5213:20–5214:5).

Days later, on November 5, 2021, the government noticed its intent to file an amended Bill of Particulars ("Amended BoP"). Ex. 16 (11/5/21 email from Kelly Volkar). The Amended BoP added the CBC assay to the list of assays that "Theranos experienced accuracy and reliability problems with." The government's amendment of the BoP is intended to facilitate the admission of testimony by Patient B.B. in Mr. Balwani's trial, but it does not cure the issue that the government cannot establish that Patient B.B.'s CBC test was performed on a Theranos proprietary device. If the Court allows Patient B.B. to testify because the CBC assay is now in the Amended BoP, the Court would be allowing the government to amend the Indictment with the Amended BoP. The resulting testimony by Patient B.B. about the accuracy and reliability of his first CBC test, without evidence clearly establishing that it was run on "Theranos's technology," would potentially expand the scope of the charges against Mr. Balwani to include allegations of the accuracy and reliability of non-Theranos technology.

An indictment cannot be amended without resubmission to the grand jury (except as to form). *Russell v. United States*, 369 U.S. 749, 770 (1962). The court may not "alter the material and essential nature of an indictment or broaden the offense charged" via the BoP. *United States v. Dawson*, 516 F.2d 796, 804 (9th Cir. 1975). The Ninth Circuit has held that where a BoP broadens the charges in the indictment, it is an impermissible amendment to the indictment. *United States v. Pazsint*, 703 F.2d 420, 423 (9th Cir. 1983). "Amending the indictment . . .

[2] Mr. Balwani also adopts, by reference, Ms. Holmes' motion insofar as the government later seeks to offer evidence regarding assays not listed in the Amended BoP. *See* Dkts. 568, 798.

constitutes a per se reversible error." *United States v. Davis*, 854 F.3d 601, 605 (9th Cir. 2017).

To amend the indictment without representment to the grand jury in order to include CBC blood tests run on non-Theranos technology is improper. Evidence to suggest that non-Theranos technology was inaccurate and unreliable as a basis to substantiate wire-fraud charges against Mr. Balwani was not put before a grand jury, and as a result cannot be put before this petit jury.

C. Portions of the CMS Form 2567 and Cover Letter Must Be Excluded

Mr. Balwani also moves to exclude evidence regarding the deficiency findings and conclusions by the CMS surveyors not directly related to the accuracy and reliability of "Theranos's technology." These include the finding that the "deficient practices of the laboratory pose immediate jeopardy to patient health and safety" ("immediate jeopardy finding"), as well as any corresponding language and findings related to the immediate jeopardy finding, because the immediate jeopardy finding was based on tests run on unmodified commercial devices.[3] For the Court's reference, Mr. Balwani has attached proposed redactions (in the form of highlighting) to the CMS Survey report and cover letter that the government admitted in Ms. Holmes' trial.[4] Ex 17 (Holmes Tr. Ex. 4621A) (redacted); Ex. 18 (Holmes Tr. Ex. 4621B) (redacted). Mr. Balwani's proposed redactions are designed to eliminate CMS findings that are unrelated to alleged issues with Theranos technology and thus beyond the scope of the charges in this case.

On January 25, 2016, CMS sent a letter ("the cover letter") to Theranos documenting its findings following its September to November 2015 inspection of the Theranos Newark lab for compliance with regulations promulgated pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"). The letter attached a Form 2567 Statement of Deficiencies ("Form 2567"), listing all the deficiencies CMS found in the clinical lab during the inspection. During Ms. Holmes' trial, the government admitted the cover letter and an excerpt of the Form 2567 into

[3] Mr. Balwani also adopts, by reference, Ms. Holmes' Motion to Exclude Evidence of CMS Survey Findings and Sanctions under Rules 401–403 and 801–803, as well as her motion to partially redact certain government agency reports, including Form CMS-2567 and corresponding cover letter. *See* Dkts. 574, 897.

[4] Mr. Balwani has a good faith basis to believe that the government will seek to admit the same excerpts of the CMS Survey in his trial that it did in Ms. Holmes' trial through former lab director Dr. Kingshuk Das. To the extent the government seeks to admit any other portions of the CMS Survey during Mr. Balwani's trial, Mr. Balwani reserves his right to object.

evidence through the testimony of former lab director Dr. Kingshuk Das. Exs. 19–20 (Holmes Tr. Ex. 4621A; Holmes Tr. Ex. 4621B).

More specifically, the government elicited through Dr. Das's testimony the conclusion from CMS that "based on the condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety." Ex.19 (Holmes Tr. Ex. 4621A). The CMS finding in the excerpt of the Form 2567 that the government offered in Ms. Holmes' trial related to the non-compliance of Hematology (labeled D5481) is centered on alleged issues with the PT/INR assay, a test run on non-Theranos technology.[5] This is shown by the CMS survey report itself, which specifically states that the agency's complaint related to the PT/INR test run on a device called the Siemens BCS XP Instrument—a non-Theranos unmodified FDA-cleared commercial device running assays purchased from Siemens. Ex. 20 (Holmes Tr. Ex. 4621B); *see also* Ex. 21 (Government trial exhibit 4982) (PT/INR Patient Impact Assessment) ("Theranos uses the Siemens BCS-XP instrument for running the PT/INR assay.").

Because the immediate jeopardy finding is based on the deficiencies related to the accuracy and reliability of PT/INR, and PT/INR does not relate to the accuracy and reliability of "Theranos's technology," the highlighted portions of the CMS cover letter and Form 2567 must be excluded. For the same reasons as outlined above under Rules 104, 401, 402, and 403, this evidence is inadmissible.

Unless the government can lay sufficient foundation linking the immediate jeopardy finding and finding D5481 in the CMS cover letter and Form 2567 to the accuracy and reliability of "Theranos's technology," the requirements of Rule 104(b) are not met, and the evidence is inadmissible. *See* Fed. R. Evid. 104(b); *Huddleston*, 485 U.S. at 690. Moreover, evidence from CMS regarding the accuracy and reliability of non-Theranos technology has no bearing on the

[5] Dr. Das testified that the CMS immediate jeopardy finding is based on the alleged deficiencies in the Theranos clinical lab related to Condition D5024: Hematology. Ex. 1 (11/9/21 Trial Tr. 5804:12–17, Ex. 19 (Holmes Tr. Ex. 4621A). Because the government only offered an excerpt of the Form 2567 which referenced Condition D5481 related to PT/INR, Mr. Balwani only moves to redact finding D5481. However, if the government seeks to admit a different or larger excerpt of the Form 2567 in his trial, he reserves the right to object to other findings related to Hematology and otherwise on the same grounds.

accuracy and reliability of "Theranos's technology," as charged in the Indictment, which requires its exclusion under Rules 401 and 402. *See* Fed. R. Evid. 401, 402.

Finally, evidence from a federal regulator that certain testing offered at Theranos that was processed on unmodified commercial devices posed immediate jeopardy to patients is highly prejudicial when used as evidence to support—albeit improperly—the wire-fraud case against Mr. Balwani. *See* Fed. R. Evid. 403. That language is sensational enough that there is risk that a jury could decide to convict Mr. Balwani based on that evidence alone. *See McFayden-Snider*, 552 F.2d at 1184. Moreover, if this evidence were admitted, the jury would again be required to parse the findings in the CMS reports to determine what was relevant—that is, run on "Theranos's technology"—and what was not. The evidence in the Form 2567 is highly technical in nature for a lay jury to parse through. Evidence that works to confuse the jury is squarely disallowed by Rule 403. *See* Fed. R. Evid. 403; *Robertson*, 875 F.3d at 1296. Cross examination is not sufficient to cure the prejudice against Mr. Balwani. This Court should adopt Mr. Balwani's proposed redactions and exclude the evidence from the CMS cover letter and Form 2567 related to the accuracy and reliability of unmodified commercial devices.

III. CONCLUSION

The government's allegations against Mr. Balwani regarding the accuracy and reliability of testing at Theranos are squarely limited to testing on "Theranos's technology." Evidence about the risk to patients posed by allegedly inaccurate and unreliable testing using non-Theranos technology has no place in this trial. For these reasons, Mr. Balwani seeks to exclude testimony from Patients E.T. and B.B., and the findings and conclusions reflected in the January 25, 2016 CMS Form 2567 and cover letter not directly tied to "Theranos's technology," including those related to PT/INR testing, and any and all other evidence the government may offer that it cannot link to the accuracy and reliability of Theranos technology.

MOTION IN LIMINE NO. 2 TO EXCLUDE EXPERT TESTIMONY OF DR. DAS

Mr. Balwani moves to exclude the testimony of Dr. Kingshuk Das because his expected testimony is based on his review of unidentified data that was stored in Theranos' LIS. Regardless of whether the government formally qualifies him as an expert, Dr. Das is in fact an expert medical doctor specializing in clinical pathology, presents to the jury as such, and the defense anticipates that the government plans to elicit expert scientific conclusions based on his analysis of data about the accuracy and reliability of the technology used in Theranos' clinical lab. This testimony is inadmissible under the Due Process and Confrontation Clauses of the United States Constitution and Federal Rule of Evidence 702. Dr. Das' opinions and conclusions rely heavily on his review of data from Theranos that the government has never identified. The LIS was of course the central repository of data relating to Theranos' laboratory operations, but that data is no longer available for the defense to assess Dr. Das' views or challenge him in any way. Without identification of and access to the data Dr. Das reviewed relating to the accuracy and reliability of Theranos technology, the defense—and the jury—will be left in the position of just having to take Dr. Das' word for it. The defense and jury are in this position because of the government's failure to obtain the LIS data. The government's claims in Ms. Holmes' case—that it could not have obtained this data because it was missing an encryption key, *see, e.g.*, Dkt. 846 at 6-7—are completely false, as demonstrated by the declaration of Richard Sonnier accompanying this motion.[6] Allowing Dr. Das to testify under these circumstances violates the law and would infect Mr. Balwani's trial with error going directly to the falsity element of the wire fraud charges.

[6] At this time, Mr. Balwani presents the Sonnier Declaration in support of motions in limine. Mr. Balwani has also moved for the same ruling this Court made in Ms. Holmes' case—that the government may not present evidence of who is at fault for failing to secure the LIS, and a defense argument that the government failed to meet its burden of proof does not open the door to fault evidence. *See* Dkt. 798 at 57-58. If Mr. Balwani introduces evidence at trial that the government is at fault, the defense acknowledges there would then be a question regarding what, if any, evidence of fault the government could introduce in rebuttal.

I. ARGUMENT

A. Dr. Das Is an Expert Witness Regardless of the Government's Label

At the Holmes trial, the government engaged in the fiction that Dr. Das was a lay witness. The government may try this again at Mr. Balwani's trial, or it may seek to qualify him as an expert without identifying the data he relied on. Either way, we anticipate the government will try to elicit expert testimony from Dr. Das going to the heart of the element of falsity in the wire fraud charges at issue, i.e., that Theranos technology was allegedly not capable of consistently producing accurate and reliable results as alleged in paragraph 16 and other portions of the Third Superseding Indictment.

The government presented Dr. Das exactly as a party would present an expert witness. Its approach followed the expert script, including his education, his board certification, and his academic appointments. Ex. 1 (11/9/21 Trial Tr. 5781–84). The government did everything but the final—and crucial—step of asking the Court to rule on Dr. Das' expert qualifications. In doing so, the government secured for its witness the perception of credibility and authority conferred on experts without first carrying its burden under Rule 702 or being subject to that rule.

In his testimony, Dr. Das repeatedly explained technical and scientific concepts to the jury. *E.g.*, *id.* at 5817 (standard deviation); *id.* at 5820 (opining on "desirable or undesirable" quality-control values and the two-standard-deviation rule); *id.* at 5831, 5847-48 (same); *id.* at 5845 (explaining a "term of art in the CLIA regulations"); *id.* at 5846 (explaining a laboratory term of art); *id.* at 5859 (describing Levey-Jennings charts); *id.* (11/10/21 Trial Tr. 5936-37) (describing the patient-distribution analysis and its goals). And as Dr. Das expressly recognized, the analysis he presented on Theranos' data was "pretty sophisticated" and "not something that in [his] view someone without knowledge and training would be in a position to do." *Id.* (11/9/21 Trial Tr. 5837); *accord id.* (11/10/21 Trial Tr. 5953) (agreeing that "many of the analyses that you were doing were pretty technical in nature").

Regardless of whether the government formally calls Dr. Das as an expert witness, he is an expert witness, and that is the way his testimony will be viewed by any rational jury. As explained in more depth in Mr. Balwani's motion on expert testimony from lay witnesses, when

"'observations' require demonstrable expertise," as Dr. Das' concededly do, that is expert testimony. *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997). It is not enough that Dr. Das made these observations or analyses in his job at Theranos: "The mere percipience of a witness to the facts on which he wishes to tender an opinion does not trump Rule 702." *Id.* Because lay witnesses may not offer opinions "based on scientific, technical, or other specialized knowledge," the Court must treat Dr. Das as the expert witness he is and apply the rules and the law accordingly regardless of whether the government moves to qualify him. Fed. R. Evid. 701(c).

B. Dr. Das' Expert Testimony Relied Heavily on His Review and Analysis of Unidentified Data Stored in LIS

Dr. Das' testimony does not just rely on specialized knowledge; it also relies on data never identified by the government. Dr. Das has expressly conceded that he reviewed "LIS . . . data dumps on his computer," Ex. 22 (US-REPORTS-0024149) at 3, as well as other data related to Theranos' Edison device, Ex. 23 (US-REPORTS-0024246), none of which the government has ever identified, Ex. 22 (US-REPORTS-0024149) at 3. And Dr. Das has repeatedly conceded that he formed his views in reliance on Theranos' patient test results and quality-control data. Ex. 1 (11/10/21 Trial Tr. 5931–32); *see also id.* at 6023; *id.* (11/9/21 Trial Tr. 5818–19, 5829, 5833–34). That data was kept in Theranos' LIS. *See, e.g.*, Ex. 24 (THPFM0003355246) at 36, 55-57 (LIS App User Guide); Ex 25 (Fosque Tr. 56-75, 83, 109); Ex. 26 (Variam Tr. 48–54). The government had the clear opportunity but failed to obtain this data as discussed in Section C below.

Virtually every aspect of Dr. Das' testimony about Theranos testing and technology derived from his review and analysis of data never identified by the government. His opinion that the quality-control data for vitamin B12 and vitamin D was undesirable—that data was in LIS. *See* 11/9/21 Trial Tr. 5846-48. The same goes for his opinion that the prostate-specific antigen test was yielding anomalous results for female patients, *id.* at 5823–24, his determination that patient prothrombin-time tests were run after quality-control failures, *id.* at 5855–56, and his observation that patient results were reported despite "10x" quality-control errors, *id.* at 5858.

These are just a few examples. In responding to CMS, Dr. Das' conclusions pervasively and by necessity relied on data that was in LIS. Most glaringly, as discussed further below, Dr. Das' bottom-line conclusion—that patient test results should be voided given his concerns—was the direct result of his review and analysis of data stored in LIS that the government has never identified.

C. The Government Has Presented Inaccurate Information to the Court Regarding Its Failure to Obtain LIS Data

In pretrial litigation with Ms. Holmes, the government claimed that the LIS data was not accessible because Theranos failed to provide a private encryption key when it produced a copy of the LIS data to the government in August 2018. Decl. of Richard L. Sonnier III ("Sonnier Decl.") ¶ 10 (citing Dkt. No. 887). And based on the government's representations, the Court concluded that when Theranos disassembled its LIS in winding down its operations, it "destroy[ed] the key and render[ed] the original database unusable." Dkt. No. 887 at 12.

The government's representations are untrue. Had the government obtained possession of the servers and other hardware that housed and ran the LIS system, or even the disk drives containing the LIS database, the "private encryption key *would not* have been necessary" to access the data. Sonnier Decl. ¶ 11. This was true both before and long after Theranos disassembled its LIS servers at the end of August 2018. The government had a straightforward means to access LIS data either before the Theranos shutdown or long afterward; it simply needed to obtain the server or disk drives that had been operating at Theranos and that were placed in storage after August 2018. *Id.* ¶ 17. It failed to do so. Had the government obtained these items, "[n]o private encryption keys would have been needed," and the defense would now have the data to test Dr. Das' opinions, among other uses of the information. *Id.*

The government is wrong that it could not have accessed the data after Theranos disassembled the system at the end of August 2018. Although the Court accepted the government's claim that the Theranos shutdown rendered the data permanently inaccessible, the government's claim is false. The LIS hardware was kept in Theranos storage after it was disassembled. *Id.* ¶ 20. The disk drives were also stored. There was nothing stopping the

government from obtaining either or both of these items from the storage locations. Had the government bothered to do so at any time before or long after Theranos disassembled the system, "it would have been a straightforward technical task to reassemble the LIS system, and no password for the private encryption key would have been needed." *Id.* With the LIS servers or disk drives in hand, "[a] technical specialist could have readily reassembled the LIS system" and recovered the data as if the system's architecture had never been disassembled. *Id.* ¶ 19. The government had the ability to obtain the data. It can no longer hide behind its false claim that Theranos destroyed the system or that the government was helpless without the encryption key. As discussed in the previous motion practice, *see* Dkt. 810 at 5–7; Dkt. 850 at 6–11, it is inexplicable and inexcusable that the government brought a laboratory fraud case without obtaining the central repository of laboratory data.

Exposure of the government's false claim that it could have done nothing to obtain the LIS is only the latest revelation in the history of the government's decision to bring a scientific fraud case without even first trying to review and analyze the central repository of scientific evidence. On May 23, 2018, about a year and a half after it learned of LIS, the government was specifically warned by WilmerHale attorneys that "it was not feasible to simply provide a copy of the LIS database, because they would not have the experience with the system to understand how to compile the data they wanted." Ex. 27 (WH000002070). The government ignored that warning and, rather than seek the assistance of experts, sought a copy of LIS with a grand jury subpoena to Theranos issued on June 4, 2018. It then charged ahead and indicted this case on June 14, 2018 before it received the LIS copy or even knew whether it would receive it. *See* Dkt. 469. In October 2018, a government Automated Litigation Support supervisor advised the prosecution team that it should marshal more resources to work on access to the LIS. Ex. 28 (10/29/20 letter ¶ 46). As demonstrated by Mr. Sonnier's declaration, the government's decision to ignore that advice led directly to the loss of the evidence. Sonnier Decl. ¶¶ 11-13, 17–21; *see also* Dkt. 850 at 7-8.

D. Without the LIS Data, Dr. Das' Testimony Should Be Excluded

The Court's role as evidentiary gatekeeper requires it to exclude Dr. Das' testimony going

to the accuracy and reliability of Theranos technology. The Court can admit that testimony only if it concludes that it "is based on sufficient facts or data," Fed. R. Evid. 702(b), and that "the expert has reliably applied [reliable] principles and methods to the facts of the case," Fed. R. Evid. 702(d). The Court must conduct the Rule 702 assessment; it cannot rely on a witness's own assurances. *See, e.g.*, Fed. R. Evid. 702 advisory committee's notes on 2000 amendment (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) ("[A] trial court 'may conclude that there is simply too great an analytical gap between the data and the opinion proffered.'").

Without access to the LIS data that Dr. Das reviewed to formulate his opinions, the Court simply cannot make these required findings and find Rule 702 satisfied. For that reason, trial courts refuse to permit expert testimony based on absent data. *E.g.*, *United States v. Sheppard*, No. 5:17-CR-00026, 2021 WL 1700356, at *5 (W.D. Ky. Apr. 29, 2021) ("Absent the data supporting the claimed results, the results are not reliable."); *Kriedler v. Pixler*, No. C06-0697RSL, 2010 WL 1507888, at *1–2 (W.D. Wash. Apr. 14, 2010); *see also Donahue v. Barnhart*, 279 F.3d 441, 446 (7th Cir. 2002) ("[A]n expert is free to give a bottom line, provided that the underlying data and reasoning are available on demand."); *Gen. Elec.*, 522 U.S. at 146 ("But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Rules 703 and 705 are not to the contrary. The former permits an expert to opine on inadmissible evidence, and the latter explains that the expert is not required to explain the underlying facts or data before offering the opinion. These rules concern what may and must be presented to the factfinder *at trial*; they do not absolve a trial court of its *preliminary* responsibility to assess the facts and the reliable application of expert methods to those facts. *See* Fed. R. Evid. 104; *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993). Moreover, Rule 705 provides that "the expert may be required to disclose those facts or data on cross-examination." Fed. R. Evid. 705. An expert like Dr. Das who cannot satisfy that disclosure requirement on cross-examination should be excluded. *E.g.*, *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012) ("[O]f course, an expert who plans to testify to an opinion must make the basis of that opinion available for evaluation by the court and opposing parties."); *accord* Fed. R.

Evid. 705 advisory committee's note (explaining that the rule "assumes that the cross-examiner has the advance knowledge which is essential for effective cross-examination").

The same result is required by the Constitution's Due Process and Confrontation Clauses. A criminal defendant must be permitted to evaluate the data underlying an expert's testimony and then cross-examine the expert about it. "[C]ross-examination is necessary not only to test the witness's knowledge and competence in the field to which his testimony relates by also to elicit the facts on which he relied in forming his opinions." *Proffitt v. Wainwright*, 685 F.2d 1227, 1254 (11th Cir. 1982). Permitting an expert to offer testimony based on absent data insulates his opinions from meaningful cross-examination by the defendant as required by the Constitution. *See, e.g.*, *Howard v. Walker*, 406 F.3d 114, 127 (2d Cir. 2005); *United States v. Love*, 482 F.2d 213, 218–19 (5th Cir. 1973).

As an example, Dr. Das testified that he reviewed the Theranos data including the absent LIS data and concluded that the patient test results were undermined by what in his view were poor results from validation and quality control, as well as his mathematical analysis of the aggregate patient results. *See, e.g.*, Ex. 1 (11/9/21 Trial Tr. 5826, 5830–34; *id.* (11/10/21 Trial Tr. 6023). For instance, Dr. Das explained that upon reviewing the quality-control data, "the average values of quality control, the targets that we were trying to reach, or that the laboratory was targeting, were being shifted unexplainedly." *Id.* (11/9/21 Trial Tr. 5831). Dr. Das further explained that "there was a lot of imprecision noted" in the quality-control data, and that this imprecision was "undesirable" in his view. *Id.* at 5831.

Yet Dr. Das never identified a single error in any patient test result. As the Theranos response to CMS acknowledged, "the fraction of patient results truly impacted, and the nature and magnitude of any effects are unknown." *Id.* at 5833. There was merely a "*possible* patient impact." *Id.* at 5832 (emphasis added). This speculation, based on Dr. Das' review of the LIS data, became the "rationale for voiding the[] tests" performed on Theranos devices. *Id.* at 5833. As explained more fully below in Mr. Balwani's motion in limine concerning Theranos' voiding of patient test results, testimony about that decision to void should be excluded for a number of reasons, including because the decision was based, at least in part, on the absent LIS data. *Id.*

at 5833–34; 11/10/21 Trial Tr. 6023.

Dr. Das' testimony on this matter encapsulates why the jury must not hear his opinions without the defense having access to the underlying data. His vague assertions about errors in patient testing results—"possible" and "unknown"—are cloaked in the authority of an expert and cannot be tested on cross-examination by way of the actual test results and data. Instead, the jury must accept the ipse dixit of the expert. As the gatekeeper, the Court must prohibit such testimony from reaching the jury in the first place.

II. CONCLUSION

For these reasons, the Court must exclude the testimony of Dr. Das that goes to the accuracy and reliability of Theranos technology. Labeling Dr. Das as anything other than an expert would be pure fiction. The law prohibits this testimony in the absence of identification and access to all the data underlying Dr. Das' opinions and views about Theranos technology.

MOTION IN LIMINE NO. 3 TO EXCLUDE EVIDENCE OF THERANOS' VOIDING TEST RESULTS

To "encourag[e] people to take . . . steps in furtherance of added safety," the law of evidence prohibits evidence of subsequent remedial measures offered to prove "culpable conduct" or "a defect in a product or its design." Fed. R. Civ. P. 407 & advisory committee's note on proposed rule. Yet that is exactly what the government seeks to introduce against Mr. Balwani by offering Theranos' voluntary decision to void a percentage of its test results. Because Theranos' decision to void test results was voluntary, evidence of the voiding is inadmissible hearsay barred by Rule 407. Moreover, given the tenuous link between the decision to void results and Mr. Balwani or either of the charged schemes, Theranos' decision to void is also irrelevant and unduly prejudicial.

The Court has already recognized these concerns—reasoning that whether this evidence was admissible in the trial of co-defendant Elizabeth Holmes turned in part on whether the decision to void tests was indeed voluntary. Dkt. 798 at 35. The Court also required the government to proffer evidence tying the voiding of tests in 2016 to the conduct charged in the indictment before it could offer this evidence against Ms. Holmes.

The operative question for Rule 407 admissibility—whether Theranos had a legal obligation to void all test results from its "Edison" device or did so voluntarily—is a question of law, not fact. The agency charged with interpreting and enforcing the CLIA regulations is CMS. *See* 42 C.F.R., Ch. IV, Subchapter G. Here, the two CMS officials who inspected the Theranos CLIA lab and issued a report documenting their findings testified under oath with agency counsel present that CMS did not require Theranos to void the Edison test results. The law compels the Court to defer to this authoritative interpretation by CMS of its own regulations. *See Auer v. Robbins*, 519 U.S. 452 (1997). Rule 407 therefore mandates exclusion.

In addition, the government cannot meet the Court's requirement under Rule 403 that the government connect the proffered evidence on voiding the Edison test results in 2016 to Mr. Balwani and the charged conduct, which ended months before Theranos decided to void those results. Among other things, former Theranos lab director Dr. Kingshuk Das testified that

he had minimal interactions with Mr. Balwani. That failure alone is enough to prohibit evidence of voiding test results.

Mr. Balwani thus asks the Court to exclude this evidence from his trial.

I. FACTUAL BACKGROUND

In the survey report following its inspection, CMS did not make *any* finding about the core allegation in the government's case: whether any Theranos test was systemically accurate or inaccurate, reliable or unreliable. CMS did make findings that Theranos' CLIA lab had certain deficiencies.[7] In response to those findings, Theranos proposed corrective actions in a February 2016 letter appending its proposed responses to each of CMS' findings. *See* Ex. 32 (THPFM0004755071–73). Dr. Das explained in Ms. Holmes' trial that his role included crafting those proposed responses to CMS. Ex. 1 (11/09/21 Trial Tr. 5816:14–17).

Six weeks after this response, Theranos decided to take a more aggressive step to try to avoid CMS's threat of sanctions and wipe the slate clean. Theranos stated that "[o]ut of abundance of caution, [Theranos] voided all patient test results reported from the TPS 3.5 instruments."[8] Ex. 33 (Holmes Trial Ex. 4943). The company did not have to take this step.

The two CMS officials who surveyed Theranos testified to this exact point. First was Gary Yamamoto, an experienced CMS surveyor who had inspected hundreds of labs in his career. Ex. 37 (US-REPORTS-0007018) at 5. According to Mr. Yamamoto, CMS neither asked nor required Theranos to void test results and that he was surprised that Theranos took this step:

Q: Was the voiding of tests something that CMS was requesting or requiring?

A: No.

Q: When you learned that the company was considering voiding tests, did that surprise you in any way?

A: Yeah, it's unusual. It's an unusual remediation for deficient practices.

Ex. 34 (Yamamoto Tr. 233:11–18).

[7] Mr. Balwani addresses separate evidentiary flaws in CMS's findings above. *See* Mr. Balwani's Motion in Limine To Exclude Evidence of Accuracy and Reliability of Tests Run on Unmodified Commercial Devices.

[8] The TPS 3.5, also known as the Edison device, was no longer being used for patient testing when Theranos voided the results.

Next, Sara Bennett, the other CMS surveyor who inspected Theranos, explained that labs may take a range of corrective actions in response to a deficiency finding. Ex. 35 (Bennett Tr. 150:4–151:24; 152:24–153:14). Ms. Bennett also told the government in September 2017 that Theranos decided to void the test results and that CMS did not instruct them to do so. *See* Ex. 36 (US-REPORTS-0006781) at 6.

Mr. Yamamoto's and Ms. Bennett's statements during testimony were not off-the-cuff remarks. To the contrary, they were made under oath during sworn deposition testimony while they were testifying as the CMS officials responsible for investigating Theranos and assessing its compliance with relevant regulations. Mr. Yamamoto and Ms. Bennett were moreover represented by agency counsel throughout the deposition, who did not interject to correct or clarify the record on the testimony that Theranos was not required to void the tests. Indeed, both witnesses signed errata sheets correcting their testimony—including corrections made for "clarity"—sent by the Department of Justice with agency counsel copied. Exs. 38 & 39. They thus reflect CMS's considered position about Theranos' legal obligations.[9]

In considering whether evidence on voiding was admissible at Ms. Holmes' trial under Rule 407, the Court at first deferred ruling. The Court reasoned that "the applicability of Rule 407 [excluding evidence of subsequent remedial measures] turns on whether Theranos' decision to void the test results was voluntary or involuntary—an issue the parties strongly dispute." Dkt. 798 at 35. The Court also agreed with several of Ms. Holmes' other arguments, recognizing the risk under Rule 403 that the jury could convict the defendants "for failing to uncover laboratory issues, a negligence standard, rather than for knowingly misrepresenting false, material information during the charged conspiracy" because the decision to void test results "was not made until 2016"—after the relevant period in the Indictment. *Id.* at 37–38. The Court barred the government from introducing evidence of Theranos' voiding of test results until the government

[9] Ms. Holmes moved to exclude evidence on Theranos' voiding tests as a subsequent remedial measure under Rule 407, raising additional arguments under Rules 401–403. *See* Dkt. 572. Mr. Balwani adopts that motion, along with all related declarations, exhibits, memoranda, replies, and oral argument. He also adopts the arguments in Ms. Holmes' mid-trial submission on the issue. Dkt. 1134. Below, Mr. Balwani asks the Court to adopt its prior ruling on a different aspect of her motion—barring the government from introducing certain settlement agreements.

"clearly ties the events in 2016 to the charged conduct [and] presents a factual basis for its assertion that Theranos' decision was involuntary for purposes of Rule 407." Dkt. 798 at 35.

At Ms. Holmes' trial, the government presented what it contended was a factual basis for concluding that voiding test results was involuntary and thus admissible under Rule 407:

> With respect to the voiding, Dr. Das is the authority on this. He was the lab director at the time. And 407 applies to voluntary measures where a company on its own in a matter of being conservative decides to do something.
>
> Here under serious threat of regulatory pressure from CMS, Dr. Das concluded that there were errors in the tests. Once he concluded that, and I now have the right cite, 493.1291, required him to correct those reports and notify the patients.

Ex. 1 (11/09/21 Trial Tr. 5701:13–20); *see also id.* at 5692:13–15 ("So 407 is a red herring in this case. They were required to do this. Dr. Das will—to void the tests. He will say that.").

The government decided not to call Ms. Bennett, Mr. Yamamoto, CMS counsel, or any other CMS witness to testify about whether Theranos' decision to void the Edison test results was compelled by CLIA regulations. Instead, the government relied on Dr. Das to testify whether he "felt" like he had to take certain action under the CLIA regulation and his professional responsibilities. Ex. 1 (11/09/21 Trial Tr. 5825:17–5826:8). The government showed Dr. Das the regulation at issue and asked, "[D]id you feel that you were required to take certain action pursuant to this CLIA regulation and your professional responsibilities." Dr. Das answered, "Yes." *Id.* (11/09/21 Trial Tr. 5825:13–5826:8). Based on this testimony that was a mix of Dr. Das' legal and ethical opinions, the Court overruled Ms. Holmes' Rule 407 objection and allowed the evidence. *Id.* (11/09/21 Trial Tr.5827:13–16).

II. ARGUMENT

A. Because *Auer* Deference Mandates Following CMS's Interpretation of Its Regulatory Requirement, Voiding Tests Was a Voluntary Remedial Measure and Is Thus Inadmissible

Whether Theranos had a legal obligation to void tests in response to deficiencies identified by CMS—the dispositive issue for admissibility under Rule 407—is a question of law. Thus, no factual foundation the government could lay can make the evidence admissible. As the Court knows, witnesses may not offer legal conclusions. Indeed, the Court accepted this principle in deciding Ms. Holmes' motions in limine. *See* Dkt. 798 at 71 ("Holmes is correct that experts may

interpret and analyze factual evidence but may not testify about the law." (citing *SEC v. Capital Consultant, LLC,* 397 F.3d 733, 749 (9th Cir. 2005)). Thus, what Dr. Das subjectively believed about his legal or professional obligations to void the tests is irrelevant to the Rule 407 threshold issue of whether the voiding was required by law.

It is doubtful whether 42 C.F.R. § 493.1291(k) applied to Theranos' circumstances in 2016, months after Theranos stopped using the Edison device for patient testing. Given that the tests could not be run again to comply with § 493.1291(k)'s edict to issue corrected reports upon concluding that a test result was erroneous, it is far from clear whether this section even applied to Theranos at the time. In fact, CMS's own findings suggest that the Edison test results did not implicate § 493.1291(k) at all. The deficiency findings—in a section the government never brought to the Court's attention—refer to a § 493.1291(k) violation, but only in connection with specific patient test reports found at that time to contain an identifiable error for a specific assay, which was not even run on the Edison device: the PT/INR test. *See* Ex. 32 (THPFM0004755071) at THPFM0004755155–56; *see also* Motion in Limine to Exclude Evidence of Accuracy and Reliability of Tests Run on Unmodified Commercial Devices, *supra*. The fact that CMS was fully aware of § 493.1291(k) and did not use it anywhere in the report in connection with the Edison tests—together with the testimony of Yamamoto and Bennett that voiding the Edison test results was not required—seriously undermines the government's assertion that this regulation applied to any of CMS's findings about the Edison tests.

Even if § 493.1291(k) did apply, whether that regulation required Theranos to void all the Edison test results is at best uncertain. The text of the regulation itself does not address voiding test results; CMS's interpretive guidelines do not discuss voiding test results; and they nowhere explain whether or under what circumstances a lab may need to void results under § 493.1291(k). *See generally* Ctrs. for Medicare and Medicaid Servs., INTERPRETIVE GUIDELINES FOR LABORATORIES—APPENDIX C (Revised Feb. 2017).[10] The defense is similarly unaware of any administrative decision under the CLIA program that supports the government's view. It is far

[10] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf.

from clear that a decision to void all test results run on a particular instrument without looking at each test result report individually is covered by the regulation.

Auer v. Robbins provides that in cases of regulatory ambiguity "the agency's interpretation of the regulation receives essentially complete deference." *Carter v. Welles-Bowen Realty, Inc.*, 736 F.3d 722, 732 (6th Cir. 2013) (Sutton, J., concurring) (citing *Auer*, 519 U.S. at 461); *see also Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 149 (1991) ("[When] the meaning of regulatory language is not free from doubt, the reviewing court should give effect to the agency's interpretation so long as it is reasonable [and] the interpretation sensibly conforms to the purpose and wording of the regulations." (internal citations, brackets, and quotation marks omitted)).

Courts grant *Auer* deference to the kind of authoritative statements here. In *Auer* itself, for instance, the Secretary of Labor's interpretation of a regulation arose in the form of a legal brief rather than a formal regulatory interpretation. *See Auer*, 519 at 462. And in *Cal. Pub. Int. Res. Grp. v. Shell Oil Co.*, a judge in this District deferred to the interpretation of an agency official who testified about the standard at issue in both a declaration and a deposition. *See* 840 F. Supp. 712, 716–17 (N.D. Cal. 1993). The D.C. Circuit has also deferred to a mid-level Department of Defense official's interpretation expressed in a declaration. *See Bigelo v. Dep't of Def.*, 217 F.3d 875, 877–78 (D.C. Cir. 2000). As that court explained, *Auer* does not require the agency's interpretation to reflect its "fair and considered judgment" nor any "longstanding agency practice." *Id.* at 878. It is enough for a court to have "no reason to suppose that the interpretation of the regulations" by the agency does not represent the agency's position and that "no past practices or pronouncements" conflict with that position. *Id.*[11]

The testimony of the two CMS officials—both deposed with agency counsel present—satisfies those standards. That is enough to end the inquiry on whether voiding the test results was compelled by law. It was not. Rule 407 thus precludes admitting the evidence at trial.

Even if the Court believed, in the face of *Auer*, that Dr. Das' subjective opinion about

[11] Indeed, a court has *declined* to give *Auer* deference to CMS's interpretation in a declaration precisely because it conflicted with the declarant's deposition testimony. *See, e.g.*, *Cal. Ins. Guar. Ass'n v. Burwell*, 227 F. Supp. 3d 1101, 1114–15 (C.D. Cal. 2017).

what the law required is relevant, the government has not proffered an adequate foundation to raise this in front of the jury. Mr. Balwani has a right to a Rule 104(c) hearing to decide the threshold question under Rule 407 of voluntariness.

Dr. Das testified—in response to the government's leading and compound question—that his decision to void the Edison results turned on his professional and ethical responsibilities and the CLIA regulations, without distinguishing them. *See* Ex. 1 (11/09/21 Trial Tr. 5825:1–5826:8). This ambiguity tracks Dr. Das' most recent interview with the government. There, he explained at first that voiding the tests was voluntary, later saying it would have been "incorrect" not to void them under CLIA regulations. *See* Ex. 40 (US-REPORTS-0037957) at 3. Indeed, when Dr. Das was responding to CMS in 2016, he never invoked § 493.1291(k) in any communication with CMS, never told Ms. Holmes that he believed this regulation compelled voiding the Edison results, and did not mention this regulation in any interview with the government before the government raised the regulation with him during trial preparation in November 2021. And in fact, Dr. Das never identified a single error in any patient test result—as required by § 493.1291(k). As Theranos' communication to CMS about voiding the Edison test results reflected, "the fraction of patient results truly impacted, and the nature and magnitude of any effects are unknown." Ex. 1 (11/09 Trial Tr. 5833:1–7). There was merely a "*possible* patient impact." *Id.* at 5832:19–20 (emphasis added). To resolve the ambiguity in Dr. Das' testimony and avoid prejudicing the jury with otherwise inadmissible evidence, justice requires a hearing outside the presence of the jury to decide whether Dr. Das' testimony—if relevant at all—is enough to show that voiding the Edison results was involuntary. *See* Fed. R. Evid. 104(c).

Finally, Dr. Das' testimony on voiding tests requires expert testimony and rested in part on data that Mr. Balwani has no access to. Those circumstances justify exclusion. As Mr. Balwani details in his motion above to exclude Dr. Das' testimony, even percipient observations may come in only through an expert when they depend on "demonstrable expertise." *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997). That is especially so when it comes to Dr. Das' backward-looking expert assessment—based in part on the missing Laboratory Information System ("LIS") data that Mr. Balwani lacks—that the Edison test results were

unreliable. Dr. Das explained that the "rationale for voiding [the Edison] tests … relied on … the validation data as well as the QC data that is referenced here, as well as the patient test results that were referenced here …." Ex. 1 (11/9/21 Trial Tr. 5833:24–5834:3). But the government has failed to identify which "QC data" and "patient test results" Dr. Das relied on and which of that data is among the missing LIS information. Thus, Mr. Balwani has no way to test Dr. Das' conclusions on whether voiding the tests was necessary and thus involuntary. *See, e.g.*, *Howard v. Walker*, 406 F.3d 114, 127 (2d Cir. 2005) (noting that allowing an expert to testify based on absent data insulates the expert's opinions from the meaningful cross-examination by the defendant required by the Constitution); *Proffitt v. Wainwright*, 685 F.2d 1227, 1254 (11th Cir. 1982) ("[C]ross-examination is necessary not only to test the witness's knowledge and competence in the field to which his testimony relates but also to elicit the facts on which he relied in forming his opinions."). So even if Dr. Das' testimony were relevant to determining voluntariness, that determination cannot hinge on Dr. Das' testimony without violating the rules governing expert testimony.

In sum, the government proposes turning regulatory interpretation on its head. In any other context, government lawyers would back their own regulators' views to the hilt. Here, by contrast, the government seeks to duck its own agency's authoritative position by relying on a medical doctor to offer an expert opinion about agency interpretation of the CLIA regulations, which he is not qualified to do.

B. The Lack of Evidence Tying Voiding Test Results to Mr. Balwani and the Charged Conduct Requires Exclusion

As the Court recognized in connection with Ms. Holmes' trial, admitting evidence of voiding the Edison results raises grave concerns under Rule 403. The Court identified several "persuasive" and "legitimate" concerns in deciding Ms. Holmes' motion on this subject. To start, "admitting evidence of Theranos' decision to void tests would be unfairly prejudicial because that decision was not made until 2016 and therefore is not probative of [Mr. Balwani's] intent during 2010–2015—the years that the subject of the indictment." Dkt. 798 at 37–38. The evidence also risks "confusion of the issues because Theranos' lab practices were not placed at issue in the

indictment" and "undue consumption of time because it would require [Mr. Balwani] to present extensive evidence about the decision to void the tests, including the regulatory backdrop for CMS's actions." *Id.* at 38.

To ameliorate these worries, the Court required the government to "clearly tie[] the events in 2016 to the charged conduct" before it could introduce evidence of voiding test results. *Id.* at 35. But the government has made no showing that would satisfy this requirement for Mr. Balwani. In Ms. Holmes' trial, the government pointed to evidence introduced by Ms. Holmes about her conduct and state of mind from 2016 to 2018. *See* Dkt. 1133 at 2–3, 9–10. But there is little likelihood of similar evidence being admitted in Mr. Balwani's trial since Mr. Balwani left Theranos in Spring 2016. The rest of the government's argument in Ms. Holmes' trial centered on conversations that Dr. Das purportedly had with Ms. Holmes about the need to void tests. *See id.* at 9–10. But Dr. Das testified that he had a "quite minimum number of interactions" with Mr. Balwani. Ex. 1 (11/09/21 Trial Tr. 5794:14–22).

It is well-established that the government cannot impute the knowledge or intent of one alleged coconspirator to another. *See Phillips v. United States*, 356 F.2d 297, 303 (9th Cir. 1965) ("[S]o-called 'constructive' notice or knowledge of a circumstance, based upon the actual knowledge of a co-conspirator … has no tendency, circumstantially or otherwise, to prove criminal intent."); *see also United States v. Engelmann*, 720 F.3d 1005, 1008 (8th Cir. 2013) ("Fraudulent intent is not presumed or assumed; it is personal and not imputed. One is chargeable with his own personal intent, not the intent of some other person."). Thus, without being able to tie the voiding evidence to Mr. Balwani, the government cannot overcome what the Court called Ms. Holmes' "legitimate concerns"—shared by Mr. Balwani—about admitting the evidence about events in 2016, months after the relevant time alleged in the Indictment. Dkt. 798 at 37–38.

The lack of connection to Mr. Balwani is an independent basis to bar evidence of Theranos' voiding tests.

III. CONCLUSION

For these reasons, Mr. Balwani asks the Court to exclude all evidence of Theranos' voiding test results at trial.

MOTION IN LIMINE NO. 4 TO EXCLUDE COCONSPIRATOR STATEMENTS

Mr. Balwani moves in limine to exclude certain alleged coconspirator statements that are outside the timeframes of any conceivable conspiracies and therefore inadmissible under Rules 801 of the Federal Rules of Evidence. The government has charged Mr. Balwani and co-Defendant Elizabeth Holmes with two conspiracies: a conspiracy to defraud Theranos investors from 2010 through 2015, and a conspiracy to defraud Theranos patients from 2013 through 2016. *See* Dkt. 469, Third Superseding Indictment ("Indictment" or "TSI") ¶¶ 19–22. To prove these charges, the government has provided notice in response to a defense request that it may seek to introduce statements of several alleged coconspirators, including Ms. Holmes, pursuant Federal Rule of Evidence 801(d)(2)(E). *See* Ex. 41 (Government's 11/10/21 Letter).

For a statement to be admissible under Rule 801(d)(2)(E), the government must prove the existence of a conspiracy—which requires an agreement between two or more people—at the time the statement was made. Fed. R. Evid. 801(d)(2)(E); *United States v. Larson*, 460 F.3d 1200, 1212 (9th Cir. 2006), *adopted in relevant part on reh'g en banc*, 495 F.3d 1094, 1096 n.4 (9th Cir. 2007). However, based on its exhibit list, the government has indicated that it may seek to introduce statements made by Ms. Holmes before Mr. Balwani joined Theranos in September 2009—prior to the existence of either of the charged conspiracies. The government has also noticed its intention to offer statements pursuant to Rule 801(d)(2)(E) that were made by Ms. Holmes after Mr. Balwani formally resigned from Theranos in July 2016, as well as statements made after both of the charged conspiracies ended. *See* Ex. 41 (Government's 11/10/21 letter).[12] As discussed below, Mr. Balwani moves to exclude such statements because they do not satisfy the requirements of Rule 801(d)(2)(E).[13]

[12] As explained within, the government failed to summarize the statements it intends to offer under Rule 801(d)(2)(E) with the specificity required by Local Rule 16-1(c)(4), so Mr. Balwani is forced to address most of the government's Rule 801(d)(2)(E) evidence in generalities.

[13] While this motion focuses on Rule 801(d)(2)(E)'s requirement that a coconspirator statement be made *during* the conspiracy, Mr. Balwani reserves the right to challenge the introduction at trial of any coconspirator statements—including those discussed in this motion—on any other applicable ground, including the requirement that such statements be made "in furtherance" of the conspiracy. Fed. R. Evid. 801(d)(2)(E).

I. BACKGROUND

As noted, the Indictment charges two conspiracies: one to defraud investors and one to defraud patients. The Indictment alleges that the conspiracy to defraud investors occurred "[f]rom a time unknown but no later than approximately 2010 through approximately 2015," and that the conspiracy to defraud patients occurred "[f]rom in or about 2013 through 2016." TSI ¶¶ 19–22.

Mr. Balwani became involved with Theranos when he personally guaranteed a $10 million loan to the company in August 2009. *See* Ex. 43(Balwani-1764). He then joined the company as President and Chief Operating Officer ("COO") the next month, and subsequently served as a member of its Board of Directors. TSI ¶ 2. Mr. Balwani disengaged from Theranos in 2016. Specifically, he stepped down from his position on the Board of Directors in April 2016, resigned from his position as President and COO in May 2016, and formally cut ties with Theranos on July 7, 2016. *See* Ex. 44 (THPFM0004657612).

On November 10, 2021, the government disclosed to the defense certain coconspirator statements that it may offer against Mr. Balwani under Rule 801(d)(2)(E) pursuant to Local Rule 16-1(c)(4), which requires the government to disclose a "summary of any statement the government intends to offer under F. R. Evid. 801(d)(2)(E) in sufficient detail that the Court may rule on the admissibility of the statement." Local Rule 16-1(c)(4). The government's disclosure incorporated its Local Rule 16-1(c)(4) disclosure for the Holmes trial, which, in turn, globally incorporated any coconspirator statements appearing in the government's exhibit list, interview memoranda, and other testimony without any more detail. *See* Ex. 41 (Government's 11/10/2021 letter); Ex. 42 (Government's 6/26/20 letter to Holmes).

The specific exhibits listed by the government in its Rule 16-1(c)(4) disclosure include the transcript of Ms. Holmes' SEC interview in July 2017 (Government trial exhibit 3278) and a CNN interview that Ms. Holmes gave in August 2016 (Government trial exhibit 3224). Both exhibits post-date Mr. Balwani's employment at Theranos and post-date the two charged conspiracies.

II. ARGUMENT

A. The Court Must Determine Whether a Conspiracy Existed Before the Government Can Rely on Rule 801(d)(2)(E)'s Coconspirator Exemption

Before an alleged coconspirator's otherwise hearsay statement may be admitted under Rule 801(d)(2)(E), the government must show by a preponderance of evidence that: (1) the conspiracy existed when the statement was made; (2) the defendant had knowledge of, and participated in, the conspiracy; and (3) the statement was made "in furtherance" of the conspiracy. *See* Fed. R. Evid. 801(d)(2)(E); *Larson*, 460 F.3d at 1212. The burden is on the government to establish the existence of the conspiracy and when it took place. *See Bourjaily v. United States*, 483 U.S. 171, 176 (1987) ("[W]hen the preliminary facts relevant to Rule 801(d)(2)(E) are disputed, the offering party must prove them by a preponderance of the evidence."). This requires "independent proof of the existence of the conspiracy and of the connection of the declarant and the defendant to it."[14] *United States v. Snow*, 521 F.2d 730, 733 (9th Cir. 1975); *United States v. Weiner*, 578 F.2d 757, 768 (9th Cir. 1978) (requiring "sufficient, substantial evidence to establish a *prima facie* case that the conspiracy existed and that the defendant was a part of it"). "It is the responsibility of the judge, rather than the jury," to determine whether the government has met its burden. *United States v. Eubanks*, 591 F.2d 513, 519 (9th Cir. 1979).

B. The Court Should Exclude Any Coconspirator Statements Offered by the Government That Were Made Before Either of the Alleged Conspiracies Began

According to the government's allegations, the earlier of the two alleged conspiracies—the conspiracy to defraud investors—began "from a time unknown but no later than" 2010. TSI ¶ 20. The government has not established that a conspiracy to defraud investors or patients existed before Mr. Balwani joined Theranos in September 2009. Nor has the government identified any coconspirators who were party to any conspiratorial agreement before that time. Nevertheless, given the government's omnibus disclosure of its entire exhibit list for the Holmes

[14] The statement itself may be considered in determining whether the conspiracy existed and whether the defendant participated in it, *see Bourjaily*, 483 U.S. at 179–80, but there "must be some evidence[] aside from the proffered statements" as well, *United States v. Gordon*, 844 F.2d 1397, 1402 (9th Cir. 1988).

trial as potential coconspirator statements, Mr. Balwani has reason to believe the government may seek to introduce statements made by Ms. Holmes well before he joined the company. *See* Ex. 41 (Government's 11/10/2021 letter).

Until the government establishes the existence of a conspiracy—i.e., an agreement between two or more of the named coconspirators—to defraud investors or patients before September 2009, the government should be precluded from introducing statements by Ms. Holmes (or any other alleged coconspirator) under Rule 801(d)(2)(E) before that time.

C. The Court Should Exclude Any Coconspirator Statements Offered by the Government That Were Made After Any Alleged Conspiracy Ended and Mr. Balwani Left Theranos

Focusing on the outer time period of the charged conspiracies, the Indictment alleges that the conspiracy to defraud investors continued through 2015 and that the conspiracy to defraud patients continued through 2016. *See* TSI ¶¶ 19–22. Indeed, the government recently moved to exclude a defense witness in the Holmes trial because that witness's only apparent connection to Theranos was that he joined the Theranos Board of Directors on May 11, 2016, and thus, his testimony is "wholly irrelevant" to the allegations in the Indictment. Dkt. 1150 at 1. According to the government, therefore, the alleged conspiracy to defraud investors ended before May 11, 2016. And yet, the government's disclosures indicate that it may seek to introduce as coconspirator statements certain interviews given by Ms. Holmes after Mr. Balwani left Theranos and after the charged conspiracies ended. These statements include a July 2017 SEC interview of Ms. Holmes (Government trial exhibit 3278) and an August 2016 CNN interview of Ms. Holmes (Government trial exhibit 3224).

Because the government has not alleged—and, indeed, has now denied—that any conspiracy continued beyond May 11, 2016, the Court should preclude the government from offering pursuant to Rule 801(d)(2)(E) any coconspirator statements made after that date, including Ms. Holmes' CNN interview in August 2016 and her SEC testimony in 2017.

Alleged coconspirator statements made after mid-2016 are inadmissible for another reason: Mr. Balwani left Theranos on July 7, 2016 and was certainly not part of any alleged conspiracy after that time. This is further grounds to exclude the CNN interview in August 2016.

It is well-established that "once a party withdraws from a conspiracy[,] subsequent statements by a coconspirator do not fall within [Rule 801(d)(2)(E)'s] exemption." *United States v. Mikhel*, 889 F.3d 1003, 1049 (9th Cir. 2018) (quoting *United States v. Nerlinger*, 862 F.2d 967, 974 (2d Cir. 1988)). An alleged conspirator can withdraw from a conspiracy by taking "'definite, decisive, and positive' steps to . . . disassociat[e] from the conspiracy." *United States v. Lothian*, 976 F.2d 1257, 1261 (9th Cir. 1992) (quoting *United States v. Loya*, 807 F.2d 1483, 1493 (9th Cir. 1987)); *id.* ("abandonment of the conspiratorial agreement" constitutes withdrawal). When a conspiracy arises in the context of a business, "an employee's resignation, after which he receives no financial benefit from the company, is prima facie evidence of withdrawal." *United States v. Lovett*, 141 F.3d 1181 (9th Cir. 1998); *see also Lothian*, 976 F.2d at 1264 (prima facie withdrawal established "by the retirement of a conspirator from the business, severance of all ties to the business, and consequent deprivation to the remaining conspirator group of the services that constituted the retiree's contribution to the fraud" (quoting *United States v. Lowell*, 649 F.2d 950, 955 (3d Cir. 1981))); *see also United States v. Handler*, No. CR 78-0148-RMT, 1978 WL 5690, at *20 (C.D. Cal. Aug. 3, 1978) (citing with approval *United States v. Goldberg*, 401 F.2d 644 (2d Cir. 1968), in which defendant effectively withdrew from a conspiracy when he left his employment with the company committing fraud and notified outside parties, including customers, of his departure).

Mr. Balwani withdrew from any alleged conspiracy related to Theranos no later than July 7, 2016—when he formally resigned from the company. *See* Ex. 44 (THPFM0004657612). The central allegation in the Indictment is that Mr. Balwani conspired with Ms. Holmes to make false and fraudulent representations in an effort to solicit investments from investors and to solicit, encourage, or otherwise induce doctors to refer and patients to use and pay for Theranos' blood testing services. TSI ¶¶ 20, 22. After Mr. Balwani's departure from Theranos, he was no longer authorized or in a position to represent or solicit anything. Mr. Balwani had no decision-making authority over any aspect of Theranos after he left. Not only did he lose all authority and influence over the company, his absence likewise "depriv[ed] . . . the remaining [alleged] conspirator group of the services that constituted [his] contribution to the [alleged] fraud." *Lowell*,

649 F.2d at 955. Because Mr. Balwani withdrew from any conspiracy no later than the time when he resigned from Theranos, the Court should, at a minimum, exclude any statements offered by the government as coconspirator statements that were made after July 7, 2016.

III. CONCLUSION

For the reasons above, at a minimum the Court should exclude any statements offered by the government pursuant to Rule 801(d)(2)(E) that were made by Ms. Holmes (or other alleged coconspirators) before Mr. Balwani joined Theranos in September 2009 and after any alleged conspiracy ended and Mr. Balwani left the company in mid-2016.

MOTION IN LIMINE NO. 5 TO EXCLUDE EXPERT TESTIMONY OFFERED BY LAY WITNESSES

Acting in its role as an evidentiary gatekeeper, the Court is tasked with policing the line between lay and expert testimony. That exercise is guided by Federal Rule of Evidence 701, which permits lay witnesses to offer opinion testimony only in strictly limited circumstances. When a lay witness strays from opinions based on her own perceptions and begins applying scientific, technical, or other specialized knowledge, the Federal Rules require disclosure and qualification as an expert.

In the trial of co-defendant Elizabeth Holmes, lay testimony has sometimes crossed this line into the realm of expert opinion. Because this may recur in Mr. Balwani's trial, he moves in limine to alert the Court to this issue and to exclude lay-opinion testimony requiring specialized knowledge. The Court should grant this motion to cabin the scope of the testimony by government witnesses in compliance with Rule 701.

I. ARGUMENT

A. Lay Witnesses Cannot Offer Opinions Requiring Specialized Knowledge

To comply with Rule 701, an opinion from a lay witness must be "(a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. The distinction "incorporate[d]" into Rule 701 "is that lay testimony 'results from a process of reasoning familiar in everyday life,' while expert testimony 'results from a process of reasoning which can be mastered only by specialists in the field.'" *Id.* advisory committee's note to 2000 amendment (quoting *State v. Brown*, 836 S.W.2d 530, 549 (Tenn. 1992)).

In a case like this one, involving complex scientific and technological issues, adherence to Rule 701 is essential. Some witnesses will have personally observed scientific methods, such as blood testing, in action. Others will have observed and worked with complicated technology. But those observations alone are not enough to permit opinion testimony if that opinion is derived—even in part—from specialized knowledge: "The mere percipience of a witness to the facts on

which he wishes to tender an opinion does not trump Rule 702." *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997).

Take a canonical example: DEA agents can offer lay testimony about the actions of an individual they have investigated on suspicion of drug trafficking. But to opine that those actions "were consistent with an experienced drug trafficker" would have required them to draw on specialized knowledge about drug-trafficking practices more generally. *Id.* (*cited with approval in* Fed. R. Evid. 701 advisory committee's note to 2000 amendment). Accordingly, the Ninth Circuit found it was error to allow such testimony without qualifying the agent as an expert.

Similarly, even a treating medical provider cannot apply specialized knowledge without qualification as an expert. He could, for instance, "testify that a substance appeared to be blood." Fed. R. Evid. 701 advisory committee's note to 2000 amendment. But he could not "testify that bruising around the eyes is indicative of trauma," *id.*, nor could he interpret a medical-imaging report to opine that it shows a brain tumor, *Jerden v. Amstutz*, 430 F.3d 1231, 1239–40 (9th Cir. 2005). This type of testimony is limited to expert witnesses.

B. The Court Should Exclude Lay-Opinion Testimony Requiring Specialized Knowledge

The Court should apply Rule 701 to exclude the opinions of lay witnesses that require specialized knowledge. This Court has already faced this evidentiary issue in the lead-up to Ms. Holmes' trial. In deciding Ms. Holmes' motions in limine, the Court explained that Theranos employees may testify as percipient witnesses, but they move "from . . . percipient to expert" when they discuss "specific details of particular scientific procedures or analyses that would require specialized knowledge to understand and interpret." Dkt. 989 at 4.

At Ms. Holmes's trial there have been occasions when the testimony of lay witnesses migrated from percipient to expert testimony without objection from the defense. Although the Court did not have an opportunity to rule on the propriety of this testimony in all instances, Mr. Balwani objects to expert testimony from unqualified lay witnesses and moves to exclude it. A key example of this line-crossing is Erika Cheung, who was the government's first witness to testify about the Theranos technology at Ms. Holmes' trial and who worked at Theranos for a

total of six months in an entry-level position right out of college. Ex. 1 (9/14/21 Trial Tr. 790:4–7, 790:21–791:4). Ms. Cheung was qualified in the lab only for "very low complexity" work like "the basic operations of running lab tests." *Id.* (9/15/21 Trial Tr. 1011:4–9). Accordingly, she categorically lacks the "scientific, technical, or other specialized knowledge" required to qualify as an expert. Fed. R. Evid. 702(a). Yet she repeatedly opined on complex scientific matters and industry standards without any relevant expertise or knowledge.

For instance, in describing purported testing failures in a Theranos laboratory, Ms. Cheung explained to the jury that "it was immensely concerning to see this degree of failures because it's just not typical for a normal lab. Like, in a normal lab you would want to see less than 1 percent, right?" Ex. 1 (9/15/21 Trial Tr. 966:22–25). That is classic expert opinion from a witness unqualified to give it. It stretches well beyond Ms. Cheung's own personal observations at Theranos. It describes industry standards and expectations, which Ms. Cheung was not qualified to opine on. *Id.* (9/14/21 Trial Tr. 790:4–7, 790:21–791:4). And it provides a specific numerical comparison between what is "normal" and what she observed at Theranos—wholly inappropriate testimony for an entry-level lab technician whose only job to that point was at Theranos. "These 'observations' require demonstrable expertise" in the field of laboratory testing, but Ms. Cheung lacks any such expertise. *Figueroa-Lopez*, 125 F.3d at 1246. Rule 701 bars testimony like this from a lay witness.

In addition, when asked about the results of proficiency testing at Theranos, Ms. Cheung switched hats and functioned as a medical expert: "The reason this [test result] is important is because this could be two very different diagnoses of a particular patient. . . . [I]f this is a patient, this [test result] could be the difference between having a [vitamin D] deficiency versus being in the normal range." Ex. 1 (9/15/21 Trial Tr. 950:16–23). Ms. Cheung has no relevant medical training or experience, and as a lay witness, she had no basis for testifying about how a doctor would interpret the results of a vitamin D assay.

Asked about purported failures in quality-control checks, Ms. Cheung opined on the "obvious explanation of why the QCs were failing"—because, in her lay opinion, "the Edison devices didn't work" and weren't "performing reliably or effectively to the standards that you

would typically see for any other type of medical diagnostic." *Id.* at 923. The Ninth Circuit has explained that comparisons like this, to industry standards, cross the line between Rules 701 and 702. *United States v. Aubrey*, 800 F.3d 1115, 1129 (9th Cir. 2015) (forensic auditor could describe the accounting steps actually performed in his job but not the merits of particular accounting methods). Similarly, when opinion testimony addresses causation—like Ms. Cheung's "obvious explanation" for a complex technological problem—it is particularly inappropriate coming from a lay witness. *See United States v. Urena*, 659 F.3d 903, 908 (9th Cir. 2011).

Finally, Mr. Balwani incorporates the arguments presented by Ms. Holmes' motion in limine concerning expert testimony by treating physicians. *See* Dkt. 561. As Ms. Holmes argued, some physician testimony is inadmissible because the physicians do not meet Rule 702's standards for expert testimony on the overall accuracy and reliability of Theranos' tests. *Id.* at 12–14. Mr. Balwani agrees that this testimony should be excluded and requests that, at a minimum, the Court apply its ruling in Ms. Holmes' case to Mr. Balwani and prohibit physicians from (1) "attributing an inaccurate result to 'lab error,'" and (2) "testify[ing] about accuracy or reliability of testing overall or about any flaw in the Theranos technology." Dkt. 798 at 53.

II. CONCLUSION

For the foregoing reasons, the Court should rule in limine that the government's lay witnesses called in Mr. Balwani's trial—Ms. Cheung included—may not give opinions or testimony derived from specialized knowledge.

MOTION IN LIMINE NO. 6 TO EXCLUDE IRRELEVANT AND INFLAMMATORY TEXT MESSAGES

The government's exhibit list includes many text messages exchanged between Defendant Ramesh "Sunny" Balwani and his co-Defendant Elizabeth Holmes. In Ms. Holmes' trial, the government introduced without objection one particularly prejudicial string of text messages referencing inflammatory terms such as "the death and sex thing" and "murder" with no explanation for how they could possibly relate to this case. Because these references are not probative, and the text-message string will likely confuse, mislead, and inflame the jury regardless of whether particular words are redacted, the Court should exclude the entire text chain from Mr. Balwani's trial under Federal Rules of Evidence 401–403.[15]

I. FACTUAL BACKGROUND

During Ms. Holmes' trial, the government introduced a slew of text messages between Ms. Holmes and Mr. Balwani through witness Nimesh Jhaveri, a former Walgreens executive. Mr. Jhaveri, who has no connection to the text string below, played the role of Mr. Balwani and Mr. Schenk played the role of Ms. Holmes. *See* Ex. 1 (10/14/21 Trial Tr. 3627:14–3638:05). As part of this exercise, Mr. Jhaveri and Mr. Schenk read aloud the following text string from October 16, 2015:

- Holmes: "Sending draft Rupert email. The language about what JC said is David's language dying."
- Holmes: "Fyi."
- Balwani: "Ok."
- Balwani: "Which part is David language."
- Holmes: "The part about why I didn't want to talk to JC (his accusations) as well as the other paragraphs that weren't there before. Everything new except the one sentence I added on the new article."

[15] This motion focuses only on the text-message string discussed below. The defense does not know yet what portion of the text messages produced as PRH_0000001–PRH_0000449 (the complete text-message compilation) the government will offer at trial. If the government offers other inadmissible texts, and Mr. Balwani and the government cannot agree on appropriate redactions, Mr. Balwani reserves the right to object to their admission at trial.

- Holmes: "I am comfortable with saying ***the death and sex thing*** to Rupert bc it makes the point."
- Balwani: "Don't."
- Holmes: "Don't what?"
- Balwani: "Don't make ***the death and sex*** point. Not ok."
- Holmes: "Challenge is you saw how everyone reacted in press to me not meeting with him."
- Holmes: "They didn't think him challenging me on patents was remotely a good reason not to meet with him."
- Balwani: "But we have enuff points to say I didn't meet with him because of his false accusations and didn't have to meet with someone who was attacking me without even meeting with me. For example patents."
- Balwani: "I wouldn't open up use personal life ***or murder*** because enough people on Twitter will assume that there is something there."
- Balwani: "It's filth."
- Balwani: "And we need to get out of ***flirty***."
- Balwani: "***Filth***."
- Holmes: "Agree for sure on outside world. Even when Rupert to make point."
- Balwani: "If u feel strongly about ***murder***. But not personal life."
- Balwani: "I think it is important to send this email but doesn't help with public beating. All our partners are bailing one at a time and same with our investors."

Ex. 31 (Government Exhibit 5387C at 13) (emphasis added); Ex. 1 (10/14/21 Trial Tr. 3634:12–3635:20).[16] In recent correspondence between the parties, the government did not rule out offering the same string of text messages in Mr. Balwani's trial. Ex. 30 (Walsh email and Government response).

[16] Ms. Holmes stipulated to admitting this evidence at her trial. Ex. 1 (10/14/21 Trial Tr. 3626:23–3627:7) (admitting Exhibit 5387C). Obviously, Mr. Balwani is not bound by Ms. Holmes' trial strategy.

II. ARGUMENT

Mr. Balwani moves to exclude the text messages reproduced above because there is no hint that the italicized terms in the string could be relevant to the charges, and any probative value they offer is substantially outweighed by the danger of unfair prejudice, confusing the issues, and misleading the jury. *See* Fed. R. Evid. 401–403. And as explained below, redacting just the most offending terms is not a viable option.

A. The References to Murder, Death, and Sex Are Irrelevant

Evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401; *United States v. Curtin*, 489 F.3d 935, 943 (9th Cir. 2007) (en banc). If evidence does not pass this standard, it is inadmissible. Fed. R. Evid. 402. The text-message string at issue includes several opaque references—including "the death and sex thing," "murder," and "filth"—with no discernable meaning in the context of this case. Thus, they are irrelevant and should be excluded.

B. The Rest of the Text String Has Very Low Probative Value

The rest of the text string without the offending terms has minimal probative value. Although cryptic, Ms. Holmes and Mr. Balwani appear to be discussing a draft email to be sent to "Rupert" (presumably, Rupert Murdoch) about accusations by "JC" (presumably then *Wall Street Journal* reporter John Carreyrou, although that is unclear). Assuming this is the context, the probative value of the string is negligible. Mr. Carreyrou wrote a highly critical article about Theranos in October 2015. That Mr. Balwani and Ms. Holmes felt under attack the day after publication of the article does not add much, especially because the October 2015 article in the *Wall Street Journal* is inadmissible. *See* Dkt. 798 at 43–44 (granting Ms. Holmes' motion in limine to exclude six news articles, including Mr. Carreyrou's October 2015 article).[17]

C. The Improper References Are Unfairly Prejudicial, Confusing, and Misleading, and Redaction Is Not an Option

Without doubt, unexplained references to "murder," "death," "sex," and "filth" in a wire

[17] Mr. Balwani asks for the same relief in a separate motion below.

fraud case would be unfairly prejudicial, confusing, and misleading. This is a classic Rule 403 issue. *See* Fed. R. Evid. 403. First, the unadorned references to "the death and sex thing" are sensational. This is a wire-fraud case. The unexplained references to "murder" only amplify the prejudicial inferences. Mr. Balwani's suggestion that Ms. Holmes not "open up" about "murder" because of what "people on Twitter will assume" insinuates that the defendants are hiding their knowledge and involvement in some violent criminal activity. It is hard to imagine a more vivid example of "the old ploy of taking statements out of context," 22A Fed. Prac. & Proc. Evid. § 5217, to "arouse[] [the jury's] sense of horror, [and] provoke[] its instinct to punish," *United States v. Kenny*, 645 F.2d 1323, 1342 (9th Cir. 1981) (quoting Weinstein's Evidence ¶ 403[03] at 403–15 (1979)). These references simply confuse the issues and obscure the truth. They should be excluded.

The defendants' references to "sex" will likewise confound and distract the jury. Ms. Holmes and Mr. Balwani had a romantic relationship that the government may try to discuss at trial.[18] But it is far from clear how that relates to "the sex point" that Ms. Holmes was apparently "comfortable . . . saying to Rupert." The references to sex are unseemly and will divert the jury's attention from the issues that matter. Allowing these messages into evidence would spawn a sideshow of improper speculation about the meaning of opaque terms; it would only highlight irrelevant evidence and cause unnecessary delay. Nothing justifies injecting sensational terms and phrases without any clear meaning into this wire-fraud case.

The government may propose redacting certain terms from these texts, but redaction is not a viable option. Even if the text message string quoted above were presented without the most offending terms, the entirety of the string still would ring multiple alarm bells for exclusion under Rule 403. It is unfairly prejudicial, confusing, and misleading—easily outweighing the very low probative value of the remaining string. This is so because with the offending words and phrases redacted, the jury would be left to speculate about the missing information. *Cf. United States v. Hoac*, 990 F.2d 1099, 1107 (9th Cir. 1993) (noting risk of redactions that "invite the jury to 'fill

[18] The romantic relationship between Mr. Balwani and Ms. Holmes, if relevant, can be amply shown by other evidence, and these texts would not add to that point.

in the blanks'"). There is thus too great a risk that anyone looking at a redacted version of the text string would engage in a highly prejudicial "Mad Libs" exercise limited only by the human imagination. With or without selective redactions, this text-message string will only misguide the jury and obstruct its truth-seeking mission. All the quoted texts should therefore be excluded. *See United States v. Hitt*, 981 F.2d 422, 424 (9th Cir. 1992) ("Where the evidence is of very slight (if any) probative value, it's an abuse of discretion to admit it if there's even a modest likelihood of unfair prejudice or a small risk of misleading the jury.").

III. CONCLUSION

For these reasons, Mr. Balwani seeks an order precluding the government from introducing the text message string quoted above.

MOTION IN LIMINE NO. 7 TO EXCLUDE EVIDENCE OF MR. BALWANI'S LICENSE PLATE

Born in Prussia in 1818, Karl Marx became one of the most influential figures in the history of political theory and economics. *See* Jonathan Wolff & David Leopold, *Karl Marx*, STAN. ENCYCLOPEDIA OF PHIL. (Spring 2021 ed.), https://plato.stanford.edu/entries/marx/. His opus, *Das Kapital*—stemming from 30 years of work—highlighted how capitalist systems in Europe exploited laborers and has become a touchstone of socialist thought. *See* Gareth Stedman Jones, *In Retrospect: Das Kapital*, 547 NATURE 401, 401 (2017).

Mr. Balwani had a personalized license plate reading "DASKPTL"—an apparent reference to Marx's tome. What that has to do with whether he committed wire fraud or conspired to do so is anyone's guess. But the government has signaled its intent to offer evidence of the license plate at trial. Mr. Balwani thus moves in limine for an order precluding reference to the license plate—or the car to which it was attached—under Federal Rules of Evidence 401–403.

I. FACTUAL BACKGROUND

In its September 2020 supplemental Rule 404(b) notice, the government suggested that it may introduce evidence that "[Mr.] Balwani's Lamborghini or Porsche bore the license plate DASKAPITAL . . . for the permitted purpose of motive and intent."[19] Ex. 29 (Sept. 2020 Rule 404(b) Notice) at 83.

Mr. Balwani asked the government whether it intended to offer this evidence in an effort to avoid unnecessary motion practice. Ex. 30 (Walsh Email & Government Response). The government would not rule out the possibility that it may offer evidence of the DASKAPITAL license plate. *Id.*

II. ARGUMENT

A. Mr. Balwani's License Plate Is Irrelevant to Any Issue at Trial.

Whether intended as a heartfelt homage, a casual reference, or an ironic joke,

[19] The government placed this information under the heading "Obtaining personal benefit from position at Theranos." Ex. 29 at 81. But as the Court ruled for Ms. Holmes' trial, evidence on a defendant's wealth appeals to "class prejudice that . . . [is] unfairly prejudicial." Dkt. 798 at 8–9. Mr. Balwani adopts Ms. Holmes' motion on spending below. As the government knows, Mr. Balwani was independently wealthy before joining Theranos, and no evidence ties his car to benefits obtained from working there. This detail too should stay out of the trial.

Mr. Balwani's license plate does not support any element of the charges that he engaged in a scheme to defraud people of money or other property. On that basis alone, it is inadmissible. *See* Fed. R. Evid. 401–402. Indeed, courts exclude the content of license plates and bumper stickers on precisely that basis. *See, e.g.*, *United States v. Stone*, 852 F. Supp. 2d 820, 838 (E.D. Mich. 2012) (excluding bumper sticker reading "Remember 9-11 was an inside job" from prosecution for conspiracy to levy war on the authority of the United States as irrelevant and unduly prejudicial); *Harper v. Coates-Clark Ortho. Surgery & Sports Med. Ctr., LLC*, No. 3:05-CV-166-J-MCR, 2006 WL 2482501, at *1 (M.D. Fla. Aug. 7, 2006) (holding that evidence of a plaintiff's bumper stickers was irrelevant to her credibility or to the elements of the Fair Labor Standards Act).

The Court should bar the same type of evidence here.

B. Evidence on Mr. Balwani's License Plate Would Risks Confusing the Jury and Would Waste Time.

In decades past, the government brought Smith Act charges against persons espousing Marxist sentiments, trampling the First Amendment in the process. *See, e.g.*, Geoffrey R. Stone, PERILOUS TIMES: FREE SPEECH IN WARTIME FROM THE SEDITION ACT OF 1798 TO THE WAR ON TERRORISM 255 (2004). Now, the government seeks to take this sordid tradition in a new direction: arguing that a license plate referencing Marx—a critic of capitalist exploitation—instead reflects Mr. Balwani's greed and intent to defraud others. In other words, the government reserves the right to argue that alluding to the title of a foundational socialist text is a "crime, wrong, or act" that shows Mr. Balwani's "motive and intent" to commit fraud. *See* Fed. R. Evid. 404(b); Ex. 29 (Sept. 2020 Rule 404(b) Notice) at 83.

While silly, the argument is also prejudicial—risking a mini-trial educating the jury on critical theory and intellectual history to show just how unmoored from reality the government's position is. In similar circumstances, courts exclude the challenged evidence under Rule 403. *See United States v. Hitt*, 981 F.2d 422, 424 (9th Cir. 1992) ("Where the evidence is of very slight (if any) probative value, it's an abuse of discretion to admit it if there's even a modest likelihood of unfair prejudice or a small risk of misleading the jury."). Other courts have agreed. *See, e.g.*,

Stone, 852 F. Supp. 2d at 838; *Harper*, 2006 WL 2482501, at *1 n.1 (holding that even if the content of the plaintiff's bumper sticker were relevant, it would be excluded under Rule 403); *see also Maddox v. Venezio*, No. 09-cv-01000-WYD-MEH, 2011 WL 10961420 at 1 (D. Colo. Oct. 28, 2011) (excluding evidence of the defendant's bumper sticker and license-plate holder under Rule 403).

So too here. The license plate has no probative value, but Mr. Balwani cannot assume that the jury will know any more about political theory than the government does. Thus, exclusion under Rule 403 is proper.

III. CONCLUSION

For these reasons, Mr. Balwani asks the Court to exclude references to his personalized license plate at trial.

MOTION IN LIMINE NO. 8 ADOPTING CERTAIN MOTIONS PREVIOUSLY FILED BY ELIZABETH HOLMES

The potential evidence—and corresponding legal issues—for Mr. Balwani's trial overlaps with that of his co-defendant Elizabeth Holmes. Thus, Mr. Balwani asks the Court to adopt several pretrial rulings from the Holmes case. He also incorporates by reference the arguments in several motions filed by Ms. Holmes.

First, the Court should apply the following rulings from the Court's May 2021 Order deciding Ms. Holmes' motions in limine ("May 2021 Order") to Mr. Balwani's trial:

1. excluding evidence of the defendants' wealth, spending, and lifestyle that is outside the general nature of their positions at Theranos
2. precluding the introduction of Theranos' settlements with CMS and the Arizona Attorney General's Office
3. providing a limiting instruction for the admission of the news article entitled "Blood, Simpler," excluding the six news articles identified below, and allowing the defense to request at trial that the Court exclude other news articles not yet identified by the government
4. excluding emotional, graphic, or inflammatory evidence about the effect or potential effect on customers of inaccurate test results
5. excluding evidence of chants vilifying or blaming competing companies or journalists, and, at a minimum, excluding evidence of accusatory statements made to Walgreens employees and Theranos employees until the government shows their relevance and falsity
6. precluding the introduction of evidence or argument on the purported inaccuracy and unreliability of tests not identified in the government's Amended Bill of Particulars
7. precluding the government from raising the purported destruction of Theranos' Laboratory Information System ("LIS"), allowing the defense to argue that the lack of LIS data means that the government cannot prove its case, and deferring ruling on whether blaming the government at trial for the loss of the LIS would open the door to the government's introducing evidence that Theranos destroyed the LIS system

Second, Mr. Balwani adopts and incorporates the arguments in several of Ms. Holmes' motions that the Court either deferred or denied, for which he offers no new arguments:

1. The motion to exclude anecdotal evidence of test results (Dkt. 563)
2. The motion to exclude FDA inspection evidence (Dkt. 573)

3. The motion to exclude evidence of alleged violations of industry standards and government regulations (Dkt. 569)

4. The motion to exclude Theranos customer service spreadsheets (Dkt. 570)

5. The motion to exclude bad acts and false or misleading statements of Theranos' agents and employees (Dkt. 565)

6. The motion to exclude evidence of any settlements apart from the CMS and Arizona settlements (Dkt. 571)

7. The motion to exclude certain evidence relating to Theranos' interactions with government regulatory agencies (Dkt. 575)

8. The motion to exclude evidence of Theranos' trade secret practices (Dkt. 566)

9. The motion to exclude certain evidence and argument about third-party testing platforms (Dkt. 576)

10. The motion to exclude certain rule 404(b) evidence—including multiplexing test results and disregarding outliers, improperly setting and altering reference ranges, and withholding certain information from physicians and patients—for lack of expert support (Dkt. 564)

11. The motion to exclude the proffered expert testimony of Dr. Stephen Master (Dkt. 560)

Third, Mr. Balwani adopts Ms. Holmes' June 2021 Motion to Suppress Evidence of Customer Complaints and Testing Results as well as Findings in CMS Report. *See* Dkt. 810. Mr. Balwani acknowledges that the Court denied Ms. Holmes' motion, *see* Dkt. 887, but he urges the Court to reconsider its decision given the government's inaccurate factual assertions that the Court relied on in making that decision. Most importantly, the government could have recovered the Theranos LIS—or at least the LIS *data*—many months *after* Theranos disassembled the system. The government's failure to do so deprives Mr. Balwani of the ability to cross-examine, for instance, Dr. Kingshuk Das about his conclusions about the accuracy and reliability of Theranos' tests. It also made this vast repository of potentially exculpatory information unavailable to the defense.[20]

[20] Mr. Balwani notes the government's failures below and discusses them above in his motion to exclude Dr. Das' testimony.

I. FACTUAL BACKGROUND

The government has charged Mr. Balwani and Ms. Holmes with ten counts of wire fraud and two counts of conspiracy to commit wire fraud. *See* Dkt. 469. In March 2020, the Court severed the trials of Ms. Holmes and Mr. Balwani, with Ms. Holmes' trial proceeding first and Mr. Balwani's trial to follow. *See* Dkt. 362. Before Ms. Holmes' trial, she and the government submitted several motions in limine. Mr. Balwani was not permitted to join Ms. Holmes' motions and was not a party and was not heard in connection with any of them.[21] The Court granted, denied, or deferred these motions. *See* Dkt. 797 & 798. Ms. Holmes' trial is ongoing. In anticipation of his own trial, Mr. Balwani submits this motion to address those issues already raised in Ms. Holmes' evidentiary motions.

II. ARGUMENT

A. The Court Should Extend Several Pretrial Rulings from Ms. Holmes' Trial to Mr. Balwani's Trial

Mr. Balwani adopts the arguments in several of Ms. Holmes' evidentiary motions and asks the Court to apply its prior rulings on those motions to Mr. Balwani's trial. The arguments in those motions apply equally to Mr. Balwani, and he incorporates them by reference to avoid burdening the Court.[22]

1. Motion to Exclude Evidence on Wealth, Spending, and Lifestyle

Mr. Balwani first adopts Ms. Holmes' Motion to Exclude Evidence Concerning Wealth, Spending, and Lifestyle Under Rules 401–403. Dkt. 567. As Ms. Holmes argued, this evidence is irrelevant. Even if it were relevant, its probative value is substantially outweighed by the risk of misleading the jury, confusing the issues, and wasting the Court's time. *Id.* at 2–6.

The government has proffered no meaningful evidence of any kind of lavish lifestyle Mr. Balwani maintained because of his work at Theranos. While most evidence of wealth,

[21] The Court need not follow its prior decisions. *See Askins v. U.S. Dep't of Homeland Sec.*, 899 F.3d 1035, 1042 (9th Cir. 2018) (law of the case "does not preclude a [trial] court from reassessing its own legal rules in the same case"); *United States v. Guy*, 903 F.2d 1240 (9th Cir. 1990) (law of the case does not apply to rulings governing the severed trials of co-defendants). "This is consistent with the principle that each party is accorded a full and fair opportunity to litigate a particular issue." *United States v. Brown*, 761 F.2d 1272, 1275–76 (9th Cir. 1985).

[22] For each Holmes argument adopted by Mr. Balwani, he also adopts all supporting memoranda of points and authorities, replies, declarations, attachments, or other supporting evidence.

spending, and lifestyle disclosed by the government in its Rule 404(b) notices relates to Ms. Holmes rather than Mr. Balwani, the evidence is equally irrelevant and equally prejudicial to Mr. Balwani.

As the Court recognized, evidence of a defendant's wealth can easily slip into "[a]ppeals to class prejudice that … are unfairly prejudicial." Dkt. 798 at 8–9. The risk is especially acute in a case like this, which "implicates potentially dangerous technology" combined with "an argument concerning an individual's greed." *Id.* The Court should thus adopt its prior ruling for Ms. Holmes' trial and preclude the government from introducing any evidence referencing Mr. Balwani's wealth, spending, and lifestyle owing to his work at Theranos. *Id.* at 9 (precluding references to "specific purchases or details" of the defendants' spending).[23]

2. Motion to Exclude Evidence of Certain Settlements

Mr. Balwani next adopts Ms. Holmes' Motion to Exclude Evidence of Remedial Measures and Settlements under Federal Rules of Evidence 401–403, 407, and 408.[24] Dkt. 572. As Ms. Holmes argued, the government should be precluded from introducing evidence about the settlements with CMS and the Arizona Attorney General's Office, including any refunds associated with the latter, because it is irrelevant, prejudicial, and barred by Rule 407. *Id.* at 3–10. The same arguments apply equally to Mr. Balwani. He therefore asks the Court to adopt its ruling on this issue and prohibit the government from introducing evidence of the CMS settlement and the Arizona settlement. *See* Dkt. 798 at 39.

[23] It would be especially improper to admit evidence of Ms. Holmes' wealth, spending, or lifestyle in Mr. Balwani's trial. The government argued that such evidence is relevant to show Ms. Holmes' motive, opportunity, intent, preparation, plan, knowledge, identity, consciousness of guilt, or absence of mistake or accident under Federal Rule of Evidence 404(b). *See* Dkt. 663. Even if this evidence were admissible under Rule 404(b) against Ms. Holmes, it says nothing about Mr. Balwani's motive, opportunity, intent, preparation, plan, knowledge, identity, consciousness of guilt, or absent of mistake or accident. The government cannot impute the knowledge or intent of one alleged coconspirator to another. *See Phillips v. United States*, 356 F.2d 297, 303 (9th Cir. 1965) ("[S]o-called 'constructive' notice or knowledge of a circumstance, based upon the actual knowledge of a co-conspirator … has no tendency, circumstantially or otherwise, to prove criminal intent."); *see also United States v. Engelmann*, 720 F.3d 1005, 1008 (8th Cir. 2013) ("Fraudulent intent is not presumed or assumed; it is personal and not imputed. One is chargeable with his own personal intent, not the intent of some other person.").

[24] Mr. Balwani expands on the portion of Ms. Holmes' motion addressing remedial measures in discussing the need to exclude evidence on Theranos' voiding test results above.

3. Motion to Exclude Certain News Articles

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Certain News Articles under Federal Rules of Evidence 403 and 802. Dkt. 578. As Ms. Holmes argued, except for two of the articles whose authors are on the government's witness list (Roger Parloff and Dr. Eric Topol), this evidence implicates multiple layers of hearsay and parrots unfairly prejudicial and sensationalist commentary about Theranos. *Id.* at 2–4.

While Mr. Balwani maintains that all these articles should be excluded for the reasons in Ms. Holmes' motion, he recognizes that the Court ruled on this issue for the Holmes trial. *See* Dkt. 798 at 44. Mr. Balwani asks that the Court at least adopt its prior decision: (1) to provide a limiting instruction to ensure the jury considers the "Blood, Simpler" article by Ken Auletta solely for its effect on readers; (2) to exclude the six articles listed below as inadmissible hearsay; and (3) to allow the defense to request at trial that the Court exclude other news articles not yet identified by the government. *Id*. at 40–44.[25]

The Court rightly excluded these six articles from the Holmes trial:

- "Craving Growth, Walgreens Dismissed Its Doubts About Theranos" by John Carreyrou and Christopher Weaver, *Wall Street Journal* (May 25, 2016)
- "Hot Startup Theranos Has Struggled With Its Blood-Test Technology" by John Carreyrou, *Wall Street Journal* (Oct. 16, 2015)
- "Walgreens Scrutinizes Theranos Testing" by John Carreyrou, Michael Siconolfi, and Christopher Weaver, *Wall Street Journal* (Oct. 23, 2015)
- "Safeway, Theranos Split After $350 Million Deal Fizzles" by John Carreyrou, *Dow Jones* (Nov. 10, 2015)
- "Blood Lab that Boasts Breakthrough Goes on Defense Against its Doubters" by Katie Benner and Andrew Pollack, *New York Times* (October 2015)
- "Can Elizabeth Holmes Save Her Unicorn?" by Sheelah Kolhatkar and Carolina Chen, *Business Week* (December 2015)

See id. at 44.

If the Court does not grant the motion in whole, its decision here should provide no less

[25] In August 2021, Ms. Holmes filed a Renewed Motion to Exclude Certain News Articles, in which she moved to exclude seven more news articles. *See* Dkt. 895. The Court deferred ruling on that motion. *See* Dkt. 989 at 5. Mr. Balwani also incorporates the arguments in that renewed motion.

relief to Mr. Balwani than to Ms. Holmes.

4. Motion to Exclude Customer Impact Evidence

Mr. Balwani likewise adopts Ms. Holmes' Motion to Exclude Customer Impact Evidence Under Rules 401–403. Dkt. 562. The Court granted Ms. Holmes' motion. *See* Dkt. 798 at 52. Because the same arguments apply equally to Mr. Balwani, the Court should enter the same ruling here and bar the government from eliciting testimony that unfairly plays on jurors' emotions. This includes certain testimony introduced at Ms. Holmes' trial.

For instance, the government should be precluded from inviting Dr. Zachman to testify about: (1) the "surprise" and "sadness" reported by her patient, B.G., on B.G.'s receiving an inaccurate hCG (human chorionic gonadotrophin) test, Ex. 1 (9/21/21 Trial Tr. 1399:8–10); (2) the "very impactful" effect that B.G.'s low hCG result had on Dr. Zachman, given that she "was empathizing to [B.G.] as a woman," *id.* at 1430:20–23; and (3) Dr. Zachman's discussion with B.G. about "ways to terminate a pregnancy," *id.* at 1445:18–21. The Court should likewise bar the government from eliciting testimony from Dr. Rosendorff that "an abnormally high potassium result" "could indicate that the patient is at risk for a heart rhythm problem," *i.e.*, "arrythmia." Ex. 1 (9/24/21 Trial Tr. 1843:14–16). All this testimony crosses the line from evidence about inaccurate test results to emotional and inflammatory testimony about the impact, or hypothetical impact, of those inaccurate results. The testimony thus falls within the Court's prior ruling and should be excluded from Mr. Balwani's trial. *See* Dkt. 798 at 52.

5. Motion to Exclude Evidence of Alleged Blaming and Vilifying of Competing Companies and Journalists

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Evidence of Alleged Blaming and Vilifying of Competing Companies and Journalists under Federal Rules of Evidence 401–403 and 404. Dkt. 577. As Ms. Holmes explained, the five acts of "blaming and vilifying" competitors and journalists identified in the government's Rule 404(b) notices lack probative value and carry a substantial risk of confusing the issues and prejudicing the defense. *Id.* Two of those acts—profane chants allegedly led by the defendants—are also propensity evidence barred by Rule 404. *Id.* The Court excluded these chants from Ms. Holmes' trial. Dkt. 798 at 69–70. It should do the

same for Mr. Balwani's trial.

The other acts in the government's 404(b) notice—accusations supposedly made by Defendants to Walgreens' and Theranos' employees at an all-hands meeting, claiming that competitors were sabotaging the Walgreens rollout—relate to claims that have not been shown to be false, as required by Local Rule 16-1(c)(3). *See also* Dkt. 577 at 2–3. Mr. Balwani therefore asks, at a minimum, that the Court stick to its ruling in Ms. Holmes' trial and preclude the government from introducing these statements until the government proves their falsity and shows "why statements about potential sabotage by Theranos competitors tends to shed any light on investor fraud." Dkt. 798 at 70.

6. Motion to Exclude Evidence of Tests Not Identified in the Bill of Particulars

Next, Mr. Balwani adopts Ms. Holmes' Motion to Exclude Evidence and Argument by the Government as to the Purported Inaccuracy or Unreliability of Tests not Identified in the Bill of Particulars. *See* Dkt. 568. The arguments in Ms. Holmes' motion apply equally to Mr. Balwani. As Ms. Holmes explained, the Bill of Particulars ("BoP") identified twenty-five assays, yet the government's exhibit list includes dozens of exhibits that address tests not listed in the BoP.[26] Because a BoP serves "to define and limit the government's case," the Court should prohibit the government from offering exhibits and related testimony outside the scope of the twenty-five listed assays. *See* Dkt. 568 at 1–2.

In its May 2021 Order, the Court allowed the government to introduce "evidence or testimony about tests not listed in the Bill of Particulars for purposes unrelated to the accuracy and reliability of those tests." Dkt. 798 at 80. But the Court required the government to "provide notice of exhibits or testimony that may involve tests not identified in the Bill of Particulars prior to their introduction so that the parties and Court can address any issues, in the context of specific evidence, outside the presence of the jury." *Id.* While Mr. Balwani maintains that the Court

[26] On November 5, 2021, the government served an Amended BoP to add another blood test—"CBC panel including each of its component assays"—to the list of assays that were allegedly inaccurate and unreliable. Mr. Balwani addresses this amendment in a separate motion to exclude evidence unrelated to the accuracy or reliability of tests run on Theranos' proprietary technology, but the amendment does not affect adopting Ms. Holmes' motion or the Court's prior reasoning.

should exclude all this evidence, he asks, at a minimum, that the Court compel the government to give notice of exhibits or testimony that may involve tests not identified in the BoP before their introduction, as it did for Ms. Holmes, in the unlikely event that government can identify a legitimate purpose.

7. Evidence on Fault for the Loss of Theranos' LIS

In deciding Ms. Holmes' motions seeking to exclude the bad acts of Theranos' employees and agents and seeking to exclude anecdotal evidence, *see* Dkt. 563 & 564, the Court ruled on the admissibility of several categories of evidence about the LIS. First, the Court excluded evidence on Theranos' destruction of the LIS database as "not relevant under Rules 401 and 404(b)." Dkt. 798 at 58. Second, the Court rebuffed the government's request to "preclude Holmes from offering … arguments" that the missing LIS database is "critical to the Government's case, or [about] the statistical insignificance of individual patient or physician testimony." *Id.* Last, the Court deferred ruling on whether Ms. Holmes' arguing "that the LIS unavailable because of the Government's failure to obtain it, that argument opens the door to the Government presenting evidence of Theranos' culpability in the destruction of the LIS." *Id.*

These conclusions fit the facts about Mr. Balwani even more strongly than they do those surrounding Ms. Holmes. Mr. Balwani ceased being an officer, director, or employee of Theranos more than two years before the LIS servers were disassembled and lacked both the authority to preserve the evidence and the legal duty to do so. Consistent with its prior ruling, unless Mr. Balwani blames the government for the loss of the LIS at trial, even asserting that the government cannot prove its case without the LIS data does not open the door to any blame-shifting by the government. Importantly, while Mr. Balwani notes the government's erroneous assertions about the loss of the LIS data both here and in the motion to exclude Dr. Das' testimony above, he has not determined whether to raise those issues in trial. Thus, there is no reason to disturb the Court's earlier ruling.

B. The Court Should Reconsider Several of Its Rulings from Ms. Holmes' Trial

Mr. Balwani adopts the arguments in several of Ms. Holmes' other motions but acknowledges that the Court has either deferred or decided those issues, and he offers no new

arguments now. But he reserves the right to argue at trial that legal and factual distinctions justify excluding certain evidence despite its potential admission at Ms. Holmes' trial. As the Court has recognized, the admissibility of specific evidence—particularly "questions of foundation, relevancy, and potential prejudice"—often requires determination "in proper context" at trial. Dkt. 798 at 4 (quoting *United States v. Pac. Gas & Elec. Co.*, 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016)).

1. Motion to Exclude Anecdotal Evidence

First, Mr. Balwani adopts Ms. Holmes' Motion to Exclude Evidence of Anecdotal Test Results under Federal Rules of Evidence 401–403. Dkt. 563. As Ms. Holmes argued, anecdotal patient or physician testimony about inaccurate test results is irrelevant to whether Theranos' tests were systemically inaccurate or unreliable, and it risks confusing the issues and misleading the jury. *Id.* But the Court held that "[e]vidence of even one inaccurate result tends to show that Theranos was producing inaccurate results, even if it does not fully prove the point." Dkt. 798 at 48–49. Mr. Balwani urges the Court to reconsider this rationale.

2. Motion to Exclude FDA Inspection Evidence

Mr. Balwani adopts Ms. Holmes' Motion to Exclude FDA Inspection Evidence under Federal Rules of Evidence 401–404 and 801–803. Dkt. 573. The Court deferred ruling on Ms. Holmes' motion, but concluded that "evidence arising out of the FDA inspection of the Theranos lab in California is relevant as to [Defendants'] state of mind, intent, and knowledge regarding the alleged misrepresentations about the accuracy and reliability of Theranos' blood tests." Dkt. 798 at 11. Mr. Balwani reserves all rights but asks the Court to at least hold the government to its theory of relevance and preclude introduction of the FDA inspection evidence until the government shows by a preponderance of the evidence that the jury can connect FDA's 2015 inspections to Mr. Balwani's state of mind, knowledge, or intent at the time of the alleged misrepresentations to investors. *See* Fed. R. Evid. 104(b).

Even while denying Ms. Holmes' motion, the Court observed that "portions of the [FDA inspection] report … go beyond mere observations and include some level of analysis by FDA inspectors," and invited Ms. Holmes "to raise arguments to certain specific pieces of evidence

within the FDA inspection evidence that involve such a high degree of observer analysis that they might not be admissible under Rule 803(8)(A)(ii)." Dkt. 798 at 14–16. Ms. Holmes later moved to partially redact certain government agency reports, including Form FDA-483 for the Palo Alto Facility and Form FDA-483 for the Newark Facility. *See* Dkt. 897 at 3–5.

Mr. Balwani adopts Ms. Holmes' proposed redactions to these two FDA forms and her supporting arguments. *Id.* The Court denied Ms. Holmes' proposed redactions to the two FDA forms except for one provisionally approved redaction to Form FDA-483 (Newark) under the "Observation 1" heading. *See* Dkt. 989 at 6–7. As the Court explained, that redaction is appropriate until the government lays a foundation to connect the redacted statement (from an unidentified Theranos employee) to Ms. Holmes. *See id.* at 7. Because the same arguments apply to Mr. Balwani, he requests the same redaction should the Court allow Forms FDA-483 into evidence. There may be additional bases to redact or exclude these exhibits based on Mr. Balwani's motion above to exclude evidence on the accuracy and reliability of non-Theranos technology.

3. Motion to Exclude Evidence of Alleged Violations of Industry Standards and Regulations

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Evidence of Alleged Violations of Industry Standards and Government Regulations under Rules 401–403. Dkt. 569. As Ms. Holmes argued, the government's purported evidence—emails and testimony by Dr. Rosendorff about Theranos' compliance with regulations—is impermissible legal opinion offered by an expert. *See id.* at 2–4. This evidence is both irrelevant and prejudicial and Ninth Circuit law prohibits its introduction. *See id.* at 4–7.

The Court held that the government "cannot offer evidence detailing violations of industry standards or government regulations solely to support an element of the charged offense," but the government may introduce "statements made to Holmes which concerned perceived violations of industry standards and government regulations" "only to show notice was given to Holmes and her state of mind." Dkt. 798 at 72; *id.* ("The evidence will not be introduced for the purpose of establishing that Theranos' laboratory practices violated industry standards or government

regulations."). The Court agreed to provide a limiting instruction to the jury "dictating that this evidence is being offered only to show notice was given to Holmes and her state of mind." *Id.*

Though granting the motion in full is appropriate, the Court should at least limit the jury's consideration of this evidence to assessing notice to Mr. Balwani and his state of mind, as the Court did for Ms. Holmes in her trial. *See* Dkt. 798 at 72.

4. Motion to Exclude Theranos' Customer Service Spreadsheets

Mr. Balwani next adopts Ms. Holmes' Motion to Exclude Theranos' Customer-Service Spreadsheets under Federal Rules of Evidence 401–404 and 801–803. Dkt. 570.

The Court ruled that the government could introduce the contents of the spreadsheets to show that Ms. Holmes knew of customer complaints about accuracy and reliability but deferred deciding whether the spreadsheets are admissible for their truth (under the business records exception) before seeing the government's foundation at trial. Dkt. 798 at 74. The Court also ruled that while the government can present evidence showing that customer complaints *exist*, it cannot introduce specific details of the complaints without violating Rule 403. *Id.* The Court also agreed to instruct the jury that this evidence is "admissible only for the purpose of establishing Holmes's notice of those complaints and [not] to establish there were actual issues with Theranos' technology." *Id.* at 74–75.

If the Court allows the government to introduce portions of these spreadsheets to show Mr. Balwani had notice of customer complaints about accuracy and reliability, the Court should, at a minimum, adopt its ruling from Mr. Holmes' trial, which precludes the government from "introduc[ing] the specific details of the [customer] complaints" and agrees to instruct the jury that evidence of the spreadsheets "is admissible only for the purpose of establishing [Mr. Balwani's] notice of [customer] complaints." Dkt. 798 at 74–75.[27]

5. Motion to Exclude Bad Acts of Theranos Agents and Employees

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Alleged Bad Acts and False or

[27] Mr. Balwani also adopts the arguments in Ms. Holmes' renewed motion to admit specific customer feedback reports shared directly with him. Dkt. 1140. While the Court denied this motion orally, Ex. 1 (11/16/21 Trial Tr. 6349:25–6351:13), Mr. Balwani notes the mismatch between allowing the government to present customer complaints for a defendant's state of mind but barring evidence of positive customer feedback for the same purpose.

Misleading Statements of Theranos Agents and Employees, including related memoranda of points and authorities, and any declarations, attachments, or other supporting evidence. Dkt. 565. The Amended BoP and the government's 404(b) notices suggest that the government intends to prove its allegations in part through the statements and acts of individuals affiliated with Theranos other than Ms. Holmes, Mr. Balwani, or any of their alleged coconspirators. *See id.* at 2–5 (listing multiple examples of allegations claiming that Defendants made misrepresentations through unidentified "representatives" and "agents").

As Ms. Holmes explained, and the Court recognized, the government must establish a causal connection between each bad act or statement and Defendants. Otherwise, this evidence invites the jury to hold Defendants—as corporate executives of Theranos—vicariously liable for bad acts and statements made by potentially hundreds of the company's agents or employees. *See* Dkt. 565 at 5–8; Dkt. 798 at 61 ("guilt by association" conflicts with due process and the federal rules of evidence); *id.* at 63 (noting danger that Defendants will be held "vicariously liable for the actions of others based on nothing more than [their] influence"). The same concerns apply equally, if not more, to Mr. Balwani, who was second in command at the company.

While Mr. Balwani maintains that the evidence identified in Ms. Holmes' motion should be excluded, he asks, at a minimum, for the same protections afforded to Ms. Holmes: that the government must "come forward with proof of a sufficient connection between [the defendant] and each 'bad act' so that the Court may assess the relevance and potential prejudice of each 'bad act.'" Dkt. 798 at 63–64. He also requests the same Rule 104(c) hearing offered to Ms. Holmes. *See id.* at 64 ("Rule 104(c)(3) requires a hearing out of the presence of the jury to consider whether the Government has presented sufficient evidence of a connection to justify the admissibility of any particular bad act, to avoid Rule 403 issues.").

6. Motion to Exclude Evidence of Civil or Regulatory Settlements

Mr. Balwani adopts Ms. Holmes' Motion to Exclude Evidence of Settlements under Federal Rules of Evidence 401–403 and 408. Dkt. 571. The Court deferred ruling on the admissibility of settlement evidence in Ms. Holmes' trial until the government gives notice that it intends to introduce such evidence. Dkt. 798 at 47. Mr. Balwani maintains that this evidence

should be excluded outright for the reasons in Ms. Holmes' motion. But he acknowledges the Court's prior ruling and asks the Court to adopt, at a minimum, the same approach in his trial. If the government gives notice that it intends to introduce settlement-related evidence, the parties can then provide particularized arguments about its admissibility.[28]

7. Motion to Exclude Evidence on Interactions with Regulatory Agencies

Mr. Balwani next adopts Ms. Holmes' Motion to Exclude Certain Evidence Relating to Theranos' Interactions with Government Regulatory Agencies under Federal Rules of Evidence 401–403 and 801–803. Dkt. 575. The Court's denied Ms. Holmes' motion. Dkt. 798 at 30. Mr. Balwani reserves the right, as afforded to Ms. Holmes, to raise "further discussions on these matters, should the parties wish to specify certain exhibits … and offer new arguments as to why those particular exhibits should still be excluded." *Id.*

8. Motion to Exclude Evidence of Trade Secrets Practices

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Evidence of Theranos' Trade Secret Practices under Federal Rules of Evidence 401–404. Dkt. 566. The arguments in Ms. Holmes' motion about the admissibility of (i) evidence of Defendants fostering a culture of secrecy at Theranos, (ii) evidence of Defendants restricting access to laboratory areas within Theranos, and (iii) evidence of Defendants threatening or intimidating employees or former employees, apply equally to Mr. Balwani.

Mr. Balwani recognizes, however, that the Court denied Ms. Holmes' motion. *See* Dkt. 798 at 66. He asks the Court to at least acknowledge—as it did for Ms. Holmes' trial—that it is "incumbent upon the Government to come forward with a sufficient connection between [Mr. Balwani] and Theranos' implementation of particular trade secrets practices, including threatening and intimidating employees or former employees of the company." *Id.* Without this foundation, evidence of the company's trade secret practices should be excluded.

[28] Statements by Ms. Holmes or others during settlement negotiations may also be inadmissible for the reasons in Mr. Balwani explains in his separate motion above to exclude statements by alleged coconspirators after the alleged conspiracy had ended or Mr. Balwani's conduct proved he had withdrawn from any such conspiracy.

9. Motion to Exclude Evidence on Third-Party Testing Platforms

Mr. Balwani also adopts Ms. Holmes' Motion to Exclude Certain Evidence and Argument Regarding Third-Party Testing Platforms under Federal Rules of Evidence 401–403, 404(b), and 702. Dkt. 576. As Ms. Holmes argued, the government should be precluded from suggesting that Theranos "tampered with" or "concealed" commercially available third-party testing platforms unless the government proffers evidence to support this nefarious insinuation. *Id.* The same arguments apply to Mr. Balwani.

The Court ruled that the government may introduce "evidence related to the modifications or the tests run on third-party platforms"[29] and "what was or was not 'concealed' or shared with manufacturers of the third-party testing platforms." Dkt. 798 at 67–68. Mr. Balwani asks, at a minimum, for the same limitation entered in Ms. Holmes trial: that the government cannot "frame its evidence and argument in a way to suggest the third-party platforms were 'tampered' with unless that has been proven by appropriate evidence." *Id.* at 68.

10. Motion to Exclude Rule 404(b) Evidence for Lack of Expert Support

Mr. Balwani adopts Ms. Holmes' Motion to Exclude Certain Rule motion 404(b) Evidence for Lack of Expert Support under Federal Rules of Evidence 401–403 and 701–702. Dkt. 564. Ms. Holmes' arguments apply equally to Mr. Balwani. As Ms. Holmes argued, expert testimony is needed before these categories of evidence can be admitted: (i) "Multiplexing test results and disregarding outliers to mask inconsistency," (ii) "Improperly setting and altering reference ranges," and (iii) "Withholding important information from doctors and patients." *Id.* at 1. While Mr. Balwani adopts and preserves Ms. Holmes' arguments, he acknowledges that the Court denied Ms. Holmes' motion. *See* Dkt. 798 at 78.

11. Motion to Exclude Expert Testimony of Dr. Stephen Master

Mr. Balwani adopts Ms. Holmes' Motion to Exclude Expert Opinion Testimony of Dr. Stephen Master under Rules 401–403 and 702. Dkt. 560. Dr. Master's proffered expert

[29] As noted above, Mr. Balwani is separately seeking to exclude evidence unrelated to the accuracy and reliability of tests run on Theranos' proprietary technology, including evidence about unmodified, third-party commercial devices. If evidence "related to … the tests run on third-party platforms," Dkt. 798 at 66, implicates the accuracy or reliability of testing on unmodified third-party platforms, it should be excluded for the reasons in that motion.

opinions are unreliable and would confuse rather than aid the jury in deciding this case. Dr. Master's opinions—based largely on emails and customer complaints over limited periods—on the accuracy and reliability of various Theranos assays and of the Edison device are speculative and lack the reliability and rigor needed for expert testimony. *See id.* at 8–19. The same is true with his irrelevant and prejudicial conclusions about Theranos' conformance to industry standards. *Id.* at 19–23.

The Court declined to exclude Dr. Master's opinions on industry standards. *See* Dkt. 797 at 9. The Court similarly found that Dr. Master's opinions about one assay—Vitamin D—were reliable but ordered a *Daubert* hearing "to assess the reliability of Dr. Master's methodology, which he employed to provide testimony and opinions about chloride, potassium, bicarbonate, HIV, HbA1c, hCG, cholesterol, calcium, and sodium." *Id.* at 11. Mr. Balwani requests at least that same relief if the government intends to call Dr. Master at his trial.

C. Mr. Balwani Adopts Ms. Holmes' Motion to Suppress

Last, Mr. Balwani adopts Ms. Holmes' June 2021 Motion to Suppress Evidence of Customer Complaints and Testing Results as well as Findings in CMS Report. *See* Dkt. 810. Just as with Ms. Holmes, anecdotal evidence of customer complaints and findings of CMS should be suppressed because of the government's failure to preserve the evidence in Theranos' LIS. *Id.* at 5–7. At a minimum an evidentiary hearing on suppression is warranted, and the government should produce all documents related to its decision not to capture the LIS data. *See id.*at 7–8.

While the Court denied Ms. Holmes' motion, Dkt. 887, that denial was based in part on several incorrect assertions made by the government. As discussed in the Declaration of Richard Sonnier and Mr. Balwani's motion to exclude Dr. Das' testimony, it is not true that any private encryption key was necessary for the government to access the LIS data. *Cf.* Dkt. 887 at 5–6. In fact, no such key would have been necessary had the government obtained the LIS servers or disk drives. *See* Sonnier Decl. ¶¶ 10–13. The government could have done so either before or long after the system was disassembled in August 2018. *Id.* And crucially, contrary to the government's claims, disassembling the system in August 2018 did not destroy the LIS data. *Id.*

¶¶ 10–13, 17–19; *cf.* Dkt. 887 at 13–14.

This new evidence justifies considering the motion to suppress anew, or at least granting an evidentiary hearing.

III. CONCLUSION

This Court should adopt in some cases and reconsider in others its evidentiary rulings from Ms. Holmes' trial in determining the admissibility of evidence in Mr. Balwani's trial.

DATED: November 19, 2021

Respectfully submitted,

ORRICK HERRINGTON & SUTCLIFFE LLP

By: */s/ Jeffrey B. Coopersmith*
Jeffrey B. Coopersmith

Attorney for Defendant
RAMESH "SUNNY" BALWANI